EXHIBIT 34

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In re: Bair Hugger Forced Air Warming Products Liability Litigation — MDL No. 2666

VIDEOTAPED DEPOSITION OF YADIN DAVID, Ed.D., P.E., C.C.E.

Houston, Texas

Tuesday, August 1, 2017

Reported by:

SUSAN PERRY MILLER, RDR, CRR, CRC

JOB NO. 124787

August 1, 2017
9:16 a.m.

VIDEOTAPED DEPOSITION of YADIN DAVID, Ed.D., P.E., C.C.E., held at the offices of Thompson Coe LLP, One Riverway, Suite 1400, Houston, Texas, pursuant to Subpoena and the Federal Rules of Civil Procedure, before Susan Perry Miller, Registered Diplomate Reporter, Certified Realtime Reporter, Certified Realtime Captioner, and Notary Public in and for the State of Texas.

A P P E A R A N C E S

FOR PLAINTIFFS:
FARRAR & BALL
1010 Lamar Street
Houston, Texas 77002
By: Mark Bankston, Esq.
- and -
KENNEDY HODGES
4409 Montrose Boulevard
Houston, Texas 77006
By: David Hodges, Esq.

FOR DEFENDANTS:
FAEGRE BAKER DANIELS
90 S. Seventh Street
Minneapolis, Minnesota 55402
By: Christin Jaye Eaton, Esq.
- and -
BLACKWELL BURKE
431 South Seventh Street
Minneapolis, Minnesota 55415
By: Peter Goss, Esq.

VIDEO TECHNICIAN: Robert Birdsall

--oOo--

Y. DAVID

(Tuesday, August 1, 2017, 9:16 a.m.)

THE VIDEOGRAPHER: Good morning. This is the start of the Deposition of Yadin David, Dr. Yadin David, in the case styled In Re: Bair Hugger Forced Air Warming Products Liability Litigation, in the United States District Court for the District of Minnesota, MDL 15-2666.

The deposition today is being held at One Riverway, Suite 1400, Houston, Texas. Today's date is August 1st, 2017, and the time is approximately 9:17.

My name is Bob Birdsall, the legal video specialist, and the court reporter today is Susan Miller. We are both from TSG Reporting.

Would counsel please identify yourselves.

MR. BANKSTON: Mark Bankston on behalf of the Plaintiffs.

MR. HODGES: David Hodges on behalf of the Plaintiffs.

Y. DAVID

MS. EATON: Christin Eaton on behalf of the Defendants.

MR. GOSS: Peter Goss on behalf of the Defendants.

THE VIDEOGRAPHER: Thank you.

Court reporter, would you please swear in the witness.

(Witness sworn by the reporter.)

P R O C E E D I N G S

YADIN DAVID, Ed.D., P.E., C.C.E., having taken an oath to tell the truth, the whole truth, and nothing but the truth, testified as follows:

EXAMINATION

BY MS. EATON:

Q. Good morning, Dr. David.

A. Good morning.

Q. Could you please tell us for the record, what is your full name?

A. Yadin David.

Q. And what is your business address at this time?

A. 1111 Hermann Drive, Houston, Texas 77004.

Y. DAVID

Q. That is the address for what entity?

A. For Biomedical Engineering Consultants LLC.

Q. Do you understand that you're under oath today just as if you were in a courtroom or before a jury?

A. I do.

Q. When you answer my questions, will you use the standards and the rigor that you would use in your professional practice outside of a courtroom?

A. I will.

Q. You have been deposed before.

A. Correct.

Q. If you have any difficulty ever understanding my question or if you need clarification for my question, will you let me know, please?

A. Yes.

Q. Thank you.

And if you ever need to take a break, as long as there's not a question pending, just let me know and we can do that.

Y. DAVID

Okay?

A. I appreciate that.

Q. Thank you.

I met you briefly this morning as you walked into the room. Had we ever spoken before that?

A. No, we did not.

Q. And have you ever spoken to anyone who you believe to be attorneys for 3M in the Bair Hugger litigation or for Arizant?

A. Not as far as I know.

Q. Is there any reason, because of medication, health or any other reason, why your testimony today can't be accurate and fair?

A. No, there's none.

Q. Okay. I would like to mark as Exhibit 1, or I have marked as Exhibit 1, a copy of the subpoena to you to produce information and document -- or to produce documents.

(David Exhibit 1 marked.)

BY MS. EATON:

Q. Is this something you've seen

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before today?

A. Yes.

Q. And did you make an effort -- did you read it?

A. I did.

Q. Do you know when you received it?

A. I received it a few days ago.

Q. Have you ever made an effort to compile information responsive to it?

A. Yes.

Q. When did you make that effort?

A. Throughout my engagement with this case.

Q. Since seeing the subpoena, have you made an effort to gather materials that would be responsive to it?

A. I believe the material was already gathered.

Q. Was that your impression when you read it?

A. Yes.

Q. Okay. When you read it a few days ago, did you discover anything that in your mind should have been provided or would be

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responsive that wasn't already provided?

A. No.

Q. In what form did you believe the materials were already provided?

A. In the basic fact that I gathered all the materials that I depended upon in binders, already there is no additional material that I can bring to the table.

Q. Okay. How many binders of material did you have?

A. I need to count. It's here in the box.

Q. Oh, you have it here?

A. Yes.

Q. Okay. You have it in this room. Can you just point to the box so I can have a sense?

A. Here it is.

Q. Okay. One white box -- that one white box right there. Is that all the materials you've reviewed in connection with your work in this case?

A. Correct.

Q. Okay. Is it your understanding

that all of those materials are either cited in your report -- I'm sorry, let me separate that out.

Are there materials in that box that are not cited in your report or listed on the materials review list?

A. Everything is listed and cited one way or another.

Q. Okay. I'm going to go through it in a little more detail later, but for now, I just wanted to get that baseline.

Why did you obtain a Bair Hugger unit for purposes of your work in this case?

A. Sure. I wanted to acquaint myself with the product, with the way it is built, with its design, with the way that it is supposed to operate, and with the internal component that have Bair in this case.

Q. Had you ever seen a Bair Hugger device before you ordered the one from eBay that's described in your report?

A. I just want to correct one thing. I did not order myself. I asked counsel to order it for me.

Q. Thank you for that correction.

A. And --

Q. Before the device was obtained for purposes of your review that is described in your report, had you ever seen a Bair Hugger device before?

A. I did.

Q. Tell me about that.

A. I have been working for almost three decades in hospitals, and I recalled walking different areas of these hospitals, especially in the late '90s, that I've seen the Bair Hugger product used in patient rooms.

Q. Is that a specific memory of the late '90s as opposed to other time frames?

A. Correct.

Q. Did your profession -- okay. So you saw a Bair Hugger device in use in patient rooms.

What hospital or hospitals?

A. It would be difficult for me to pinpoint specific hospitals. I'll give you a list of a few of them that I worked at at the time that we are discussing here, and those

will be the St. Luke's Episcopal Hospital here in Houston and the Texas Children Hospital at the -- here in the Medical Center.

Q. In Houston also?

A. Correct.

Q. Okay. Those were the two hospitals you were working at at the time when you believe you saw a Bair Hugger device?

A. Correct.

Q. What was your responsibility at those two hospitals at that time, in the late 1990s?

A. I was the director of the biomedical engineering department.

Q. What does that mean?

A. That means that I have the responsibility to make sure that medical technology used in these hospitals is selected, installed, maintained, and in service properly.

Q. You said "medical technology." What does that encompass?

A. In general, that will be biomedical devices.

Q. Can you give me an example of some biomedical devices?

A. Absolutely. Biomedical devices used for managing and diagnosing patient condition will be bedside monitors that -- looking at patient vital signs. It will be X-ray machines, lasers in surgery. It will be blood-warming devices and laboratory diagnostic instruments.

Q. Is that a complete list?

A. Oh, my God, no.

Q. Okay. Those were examples?

A. I was responsible for about 25,000 devices, biomedical devices, so we probably can spend the day going through the type of biomedical device on these assets.

Q. Would the Bair Hugger device be within the type of devices that you were responsible for?

A. I do not recall.

Q. You don't recall ever making an evaluation or decision about a Bair Hugger device?

A. Correct.

Q. Would it have been within the category of biomedical devices that you -- would fall within the scope of your job?

A. Depends how it's arrived into that patient's room. If it was intended to be purchased, absolutely it would be my responsibility to review and evaluate. If it was on loan, rent, or brought by a third party, it will not be subjected to my evaluation.

Q. Do you know, at either St. Luke's or Texas Children's Hospital, if the device was purchased or brought in in some other way?

A. No, I do not.

Q. Is that distinction you've made about purchased versus brought in some other way something that would apply at both of the hospitals that you've listed, St. Luke's and Texas Children's?

A. Correct.

Q. Okay. Why do you -- are you saying there's a policy or procedure set out that that's how your responsibilities fall?

A. We did have many policies, and my

program was very well scripted and structured. There were a flexibility for especially the clinical staff to become aware of new technologies and use or review them on the loan basis or as a donation. That would be not subjected to evaluation.

Q. Did you say "clinical staff"?

A. I did.

Q. I wanted to make sure. At first I thought I heard the word "stuff" but I thought that you must have meant "staff."

A. I apologize for my accent, but I referred to people who were involved with clinical activities.

Q. Thank you. No need to apologize. I just wanted to be sure I understood you.

You're saying there was a policy of flexibility for clinical staff to use instruments that didn't come in through purchasing?

A. Correct.

Q. Was your role as biomedical engineer tied only to purchasing, then, devices purchased?

A. That's correct. My responsibility was to ensure that recommendations for commitment of hospital financial resources towards medical technology, i.e., biomedical devices, are based on several aspects that include the cost-benefit ratio analysis, risk analysis, and match between product feature and clinical needs, and that separate than trying to educate clinicians about new product or different product than they use.

MS. EATON: Can I just -- I just wanted to read one thing there, I'm sorry.

(Counsel reviewing realtime transcript on the reporter's computer.)

BY MS. EATON:

Q. I'm going to return to that history in a moment.

Had you ever -- but for now I want to return to the device that you evaluated for purposes of your work in this case.

Had you ever touched or used a Bair Hugger device before the one you obtained for your evaluation here?

A. Besides the one that I operated?

Q. I'm sorry, my question may not have been clear. For purposes of your work in this lawsuit and preparing the report that you prepared, did you obtain and review and operate a Bair Hugger device?

A. Correct.

Q. Other than -- how many Bair Hugger devices?

A. One.

Q. Other than that one, before you obtained that one, have you ever operated a Bair Hugger device before?

A. Not that I recall.

Q. Have you ever touched one before, in any way?

A. I cannot ascertain that. That does not ring a bell.

Q. You said you had a memory of having seen them in hospitals. Did you -- what is the -- can you tell me more about that memory? What do you recall?

A. No, I cannot.

Q. You recall having seen them and

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that's it?

A. Correct.

Q. Okay. Do you recall having any sense, at the time you saw them, for why they were in an operating room?

A. I mentioned it was patient room. I didn't say operating room.

Q. Oh, I'm sorry. Can you please clarify for me, where did you see one?

A. I don't recall it. I don't believe I was walking the operating room.

Q. What do you mean by "patient room"?

A. An area where a patient is being observed on one of the general floors.

Q. Is this something before or after surgery or not in connection with surgery at all?

A. I have no recollection of that.

Q. Do you have any recollection of the specific hardware -- in other words, what model it would be, how large it was, how it compares to the one that you obtained for use in this case?

A. No.

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Q. Is this a specific memory of having seen it one time, or do you believe you saw a Bair Hugger device more than one time?

A. We are talking about something that is about 20 years ago or more, so I cannot differentiate if it's one or two times. Definitely not something that would be frequent.

Q. So with the clarification that you saw it in a patient room, do you recall having any understanding at the time you saw it about why it was in the patient room?

A. No.

Q. Do you recall any discussion, ever, during your work at a hospital, about Bair Hugger devices and their use?

A. No.

Q. And I shouldn't have added those last two words, because I meant it to be a very broad question. Do you recall any conversation during your time working in any hospital about Bair Hugger devices?

A. No.

Q. Were you responsible for making any

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evaluation or assessment about disposables that are used with medical technology?

A. Yes, I did.

Q. Did you ever make any evaluation or assessment about blankets used with the Bair Hugger device?

A. I don't believe so.

Q. Did every piece of medical technology that came into an operating room become subject to an evaluation by your department, if it was purchased?

A. My ego says answer that as a positive yes so I can reflect on a very good program. I would say the first time a type of device is acquisitioned, probably it will be evaluated. But if the same device is being purchased years later and again and again, it would not.

Q. Did you start the question -- I'm sorry. Did you start your answer by saying your ego would say yes because it was a good program?

A. Yes.

Q. Okay. Meaning, in your mind, if

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you had a good program, you would want to have looked at all the devices that were being purchased?

MR. BANKSTON: Object to the form.

BY MS. EATON:

Q. Is that right?

A. The point to bring to this question is that the process in the hospital is so complex that there may be avenues that are not main street but on the perimeter the device is coming in through some kind of special relationship with a vendor, and I would not have the benefit of passing evaluation or judgment on that.

Give an example, a blood analyzer in the lab may have been purchased by buying the agents that are used in the blood-drawing process, the chemical agent. So as long as the hospital buys those chemical agents, the product is given to the hospital and there is no evaluation involvement because there's no purchasing of capital item. It's like the Schick blade; you get the holder if you buy the razor or something like that.

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Q. Within the terms of the programs at -- I'm sorry. Were you responsible for evaluating products at both Texas Children's and St. Luke's at certain times?

A. At certain times, correct.

Q. Within the program as you understand it at those hospitals, would the purchase of Bair Hugger blankets have brought the Bair Hugger device up for review by you, or not?

A. Now I'm hypothesizing with you about my response, because if you are telling me that there is requisition to buy a blanket, it sounds to me like the product is already in the hospital, so just add another accessory would not be subjected to evaluation.

Q. Do you know if Bair Hugger devices were purchased by either Texas Children's or St. Luke's Hospitals?

A. At the time that I was there, no, I don't know.

Q. Do you know if blankets were purchased?

A. No.

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Q. You don't recall evaluating a Bair Hugger device -- and I apologize if I already asked you this. Do you recall ever evaluating the blankets?

A. I do not.

Q. Had you ever disassembled a Bair Hugger device before the work you did for this case?

A. No, I did not.

Q. And do you have any memory about the way the Bair Hugger device or devices you recall having seen in the past were being operated?

A. No, I do not.

Q. Why did you choose to examine a previously used Bair Hugger device for your work in this case?

A. Actually, this is a very good question. Because usually if you would like to review the device performance, especially in a clinical setting, you would like to have a new product that is fully capable to deliver all these features.

On the other hand, my goal

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specifically was to see device operation and the inside of the device after it was used in the field. So on purposely, I wanted to get a device that had some field experience with it.

Q. Why?

A. Because it gives me a view of what the device's capability to sustain its features in the field after it's been used for a period of hours. For example -- and I pointed that in my report -- is that I looked at the four feet on the bottom of the device and gave -- and realized that this device was used much on the floor because you could see the wear and tear on those four points at the base of the device.

So a device sitting on the floor has different performance on its enclosure than a device that would be up on the shelf or on an IV pole.

Q. What do you mean, it has a difference in the enclosure?

A. The performance of the characteristics of the physical enclosure, the box that covered the whole internal operation

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and the components inside are subjected to specific wear and tear from floor, such as operating floors and recovery room floors.

Q. How does the floor and whether the device is placed on the floor or not impact the inside of the device, to your understanding?

A. There is a significant difference. A device that is placed on the floor is in closer proximity to an area that is not clean, that has higher concentration of pathogens, and that have more -- a higher percentage of relative humidity around the intake of the device. This gives rise to additional contamination of pathogens that the device can harbor.

Q. Okay. Did you examine a device that had been used and was not placed on the floor to see if the inside of the device looked any different?

A. Once again, I don't know where the device was used, but it's my observation that the bottom part of the device, the four feet, were subjected to significant wear and tear;

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therefore, it was moved about on a hard surface like a floor.

Q. I'm sorry. My question was a bit different. Did you obtain any other used device that was not used on a floor to compare the insides of the two devices and see if they looked any different?

A. I didn't see a need to do that.

Q. Did you do it?

A. If I didn't see a need to do it, I didn't do it.

Q. Okay. Thank you.

On what basis do you say that the inside of the device you examined looked any different than the inside of any other device that had been in use?

A. I don't believe that I said that.

Q. Well, I believe that you said you wanted to see an in-operation device and I believe that you said that the fact that the feet showed wear and tear was important to you because the inside would have a different environment. So maybe I should ask a different question.

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Do you believe that the operation of the Bair Hugger device you examined resulted in any difference in the inside of the compartment than would have occurred if the device had been operated in a different manner?

MR. BANKSTON: Object to the form. Object to the preamble.

A. I need to very simply clarify the purpose of my examination of the device. I wanted to see how the device is built, how it's put together, where the components physically sit, where is the intake, where is the output, how you connect the blanket to it, and I did not seek to make any performance comparison or derive any clinical outcome of the device use.

BY MS. EATON:

Q. When I asked you why you wanted a used device, you said you preferred one so that you could see its characteristics after use. Now that you describe the purpose here, let me ask a different question.

Would a new device have provided

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just as much information to you as the one that you examined?

MR. BANKSTON: Object to the form. Object to the preamble.

A. A new device would have a completely different purpose than what I was seeking. I wanted to see the device structure, how it would sustain its integrity of fitting the components together, how the filter fits into the device, where the air intake is, how close it is to a base that it's sitting on. So this was the particular reason that I wanted such a device.

BY MS. EATON:

Q. Did you know that you had available to you a new device?

MR. BANKSTON: Object to the form. Misstates the record.

A. I don't believe that I asked for a new device.

BY MS. EATON:

Q. Okay. What environment was the device that you obtained used in?

A. I didn't receive that information.

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Q. For how long had it been in use?

A. The hour meter on the device indicated, as I had written in my report, over 5,000 hours of use.

Q. Do you know how typical that length of use is?

A. No, I do not know.

Q. Do you know how that length of use may have impacted the condition of the device that you had?

A. The length of use will -- may or may not impact the device, and that's why I wanted to examine a used device, to see how well the filter mounting, for example, supports air flow, and to see can you clean the device, can you reach areas that can harbor bacteria or pathogens, and in general, to became -- to make myself acquainted with the product.

Q. Did you see any issue with the filter mounting on the device that you examined?

A. Not on that unit.

Q. Did you see anything about the

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condition of the unit you examined that did not -- let me ask that differently.

Did you see anything about the unit that you had examined that appeared to be a condition you thought had changed based on use?

MR. BANKSTON: Object to the form.

A. Can you clarify your question?

BY MS. EATON:

Q. Sure. You said you were looking to see how a device held up under use, roughly speaking. Is that right?

A. Yes.

Q. Did you see anything about the device you examined that you identified as something that might have been related to use, a condition that might have been related to use?

A. I see.

Sure. The obvious thing was lint, dirt, and accumulation of unclean particles.

Q. Anything else?

MR. BANKSTON: I object to the form.

Y. DAVID

MS. EATON: What is the objection to that question?

MR. BANKSTON: It calls for either a narrative or a complete accounting of everything that could possibly be different about the device.

MS. EATON: Yes, it kind of does. I'm asking him for his expert opinion, and I think you're making too many objections here. That is not a valid objection.

MR. HODGES: Object to the sidebar.

BY MS. EATON:

Q. Sir, did you identify anything else about the device that appeared to demonstrate a condition of use that was consistent with what you were looking for?

A. There were several observations that I made. They are included in my report and very clearly indicate that upon turning the device on, connecting it to a power source, it went through the self-test, then identification of the device models and version of the software, and then I was able

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to see that there are fault codes, I think the abbreviation displays FC. And I mentioned that in my report.

BY MS. EATON:

Q. Were all the -- I'm going to get to your report in a minute, so we'll have that fault code in front of us.

Was there a reason --

MR. BANKSTON: Objection. Object to the preamble.

BY MS. EATON:

Q. Sir, I was just letting you know where I'm going so that you would understand. I will come back to the observations that are made in your report.

MR. BANKSTON: And I'm going to object every time you don't ask a question. Object to the preamble.

BY MS. EATON:

Q. Was there a reason that you wanted a Model 750 specifically?

A. As compared to what?

Q. Any other model of Bair Hugger device?

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A. Since this is the product that I was asked to opine upon, that's the one I requested.

(David Exhibit 2 marked.)

BY MS. EATON:

Q. I've marked as Exhibit 2 the response to the subpoena that was served in this case. Have you ever seen this?

A. Not in this form.

Q. If you would turn to the middle of this packet, there is an eBay -- a printout of an apparent eBay listing. It looks like this (indicating).

A. Yes.

Q. Did you go onto eBay and look for a device?

MR. BANKSTON: Objection to form.

A. I did not.

MS. EATON: What's your objection to that question?

MR. BANKSTON: Asked and answered.

BY MS. EATON:

Q. Do you know who did?

A. Physically who did it, no. What I

know is that I requested counsel to provide me with exemplars, as we discussed earlier.

Q. What type of criteria, if any, did you request in terms of the device you wanted to see?

A. Very simply, a used device.

Q. Any other criteria you requested?

MR. BANKSTON: Objection to form.

A. No.

BY MS. EATON:

Q. Were you given more than one listing to review?

A. No.

Q. Were you given this listing contained in Exhibit 2 to review before the device was purchased to see if it met your criteria?

A. I don't believe so.

Q. Have you ever heard of Spectrum Surgical Solutions before?

A. No.

Q. In your work in hospitals, were refurbished or used medical technologies ever purchased?

A. The word "ever" called -- caught my attention. I would say, by far, all the acquisitions are of new products.

Q. Did you speak with anyone from Spectrum Surgical Solutions, Inc., about this device that you ultimately received?

A. No.

Q. And I should clarify for the record. If you turn to the page after the listing, there's reference to Spectrum Surgical Solutions in what I believe to be part of the eBay listing.

Do you know who provided the device?

A. No, I do not.

Q. Do you know if it was Spectrum -- okay. So then you don't know who, okay.

Did you ever have any interaction with any company or person who you believe ever had possession of this device?

A. Ever have possession... since I don't know where it was used, I don't believe I can answer the question.

Q. You mentioned the fault codes. How

did you see those? Did you have to do something to get them to come up or did they just pop up?

A. No. You have to enter a mode specifically for query the archive of fault codes.

Q. Is that something that -- how did you -- sorry. Let me start with a new question.

Did you obtain a user's manual with this device?

A. I don't believe so.

Q. Or an operator's manual, anything like that?

A. No.

Q. How did you know how to query the archive, then?

A. I searched literature.

Q. What literature?

A. The literature that contained manuals, operation and service manuals, for this product.

Q. Where did you look?

A. I have -- first of all, I looked at

my own library. I have a library of manuals for different medical products, and then I went online and did search.

Q. What site did you ultimate- -- I'm sorry. I take it that because you went online it was not in your library. Is that a correct assumption?

A. That is correct.

Q. Do you know what site you ultimately found the manual from?

A. No.

Q. What did you find when you searched the archive for fault codes?

A. That there are many sources for such a document. And I looked at one that seemed to be comprehensive, and it has a PDF format of the manual, and I read it before I opened the shipping box of the device and realized that there is a way to identify a fault code by query the archive.

Q. Is the PDF you just mentioned something that is specifically cited or identified in your report?

A. I read it online. I never made a

hard copy, and I don't believe that it is cited.

Q. And you don't -- is there a particular search engine or search terms I could use to replicate and find the same one that you found?

A. Easily.

Q. Can you tell me those?

A. You can go to Google and put "Bair Hugger Model 750 Manual" and you will get ample results.

Q. But if I wanted to know which result you got, is there any further point you can give me?

A. No.

Q. Do you know what year the manual is for?

A. I do not recall.

Q. Okay. How many fault codes were there?

A. Five.

Q. Did you have -- what comes up? Is it a number, a word? When the fault code comes up, what comes up?

A. It's a relatively small display of a few characters and it comes up with the capital letter F, capital letter C, brackets, with a number; and then I believe four digits.

Q. Did you have any source to interpret what those fault codes meant?

A. In the same manual, it had the codes.

Q. What were the fault code numbers that came up?

A. The three recent ones were code 50. The two prior to that, to make a complete total of five, were code 3 and code 8.

Q. Did you make notes of that somewhere, what the codes were?

A. No.

Q. At the time you originally examined the device, did you make notes?

A. No. My computer was with me and I -- after I read the manual, I opened the device under personal protection equipment and operated it and knew how to get to the code memory and look at that.

You see, the simple fact is that I

was not trying to have a device that simulated clinical utilization. My specific reason is to become familiar with the product integrity. So if I would have a device that I needed to do performance testing, I would set it up in a different environment than I used. I would have a protocol with specific tasks, and I will have a document showing the results. That was not my purpose.

Q. Is that something you have done before, what you've just described, the performance testing?

A. Sure.

Q. Okay. In what role have you done that before?

A. I'm doing that continuously for 40 years, so I've done it as a biomedical engineer, I've done it as a research assistant in anesthesia, a dog lab. I've done that as director of biomedical engineering, and I'm doing it now as a consultant.

Q. Is there one set of standards or criteria that you follow when you do that kind of performance testing, or does it vary by

device?

A. Sure, it's varied. That would be nice if all devices would have same feature and you can use one protocol, but as you well know, we -- on the street, we have trucks and we have cars and we have motorcycles and we have SUVs, and each one of them would be tested differently.

Q. Is there an overarching approach that is documented that would apply to more than one device?

A. Sure there is.

Q. Can you give me that citation? Is it in writing, I should say?

A. I don't know that there is a specific protocol so generic that you're asking about somewhere in the literature. I usually create my own protocol based on my education and experience and the device features.

Q. When you do that, are you trying to reflect the clinical use condition for the device?

A. It will be included.

Q. Why is that?
A. The purpose of a device is to have impact on clinical outcome, so one would like to know that there is a validation of the product features and the clinical outcomes by making tests that shows how well the two are matched.
Q. In doing that, is it important to assemble the device as it will be used in the clinical environment?
A. First of all, if there is something to be assembled, then the answer is yes. Not always there is any assembly required.
Q. When is the last time you looked at the Bair Hugger device that was obtained from eBay?
A. Probably during the process of writing my opinion report.
Q. Roughly, when would that be?
A. That would be March 2017.
Q. Do you have any notes of your examination of that device other than what is contained in your report?
A. No.

Q. You have carried the fault codes just in memory?
A. Correct.
Q. Okay. Did you look up what they meant, 3, 8 or 50?
A. At the time I did.
Q. Can you tell me, sitting here today, what either code 3, code 8 or code 50 means?
A. Code 50 was something about stuck key during startup. I'm trying to recollect, I'm not sure of that specific language, but something to that effect.
Code 3 and code 8, sorry, I don't remember.
Q. Is there -- I'm trying to have a sense for the significance of those codes. Was there anything about code 3 or code 8 that, to your view, would impact the performance of the device?
A. I think so. If I'm not mistaken, code 8 or code 3 has something to do with the heater. With the heater.
Q. Do you know what it had to do with

the heater?
A. I am afraid I can't recall.
Q. Was your only source of information about what the code meant this operator manual that you were looking at on the internet?
A. Yes.
Q. Did you do any other research to determine whether that fault code might impact the heating performance?
A. I don't see a need for. I did not seek clinical performance of the device as part of my protocol.
Q. Does that mean you did not do any other research to determine whether that fault code would actually impact the heating?
A. In my experience as a biomedical engineering expert, I understand or I understood at the time the code to mean that there is a problem with the heater, and since I did not set my objective to determine the performance of the device, I did not do any additional investigation on the code.
Q. Did you tell me that -- and I apologize, I'm just not sure if I'm recalling

the timeline. Did you tell me that when you first opened the device, took it out of the box and turned it on, that's when you ran the fault codes to see what they were?
A. No, I don't believe I said that.
Q. Do you recall when you ran the fault codes?
A. After I took the device to a laboratory and put it together with a blanket and operated it for the first time.
Q. On the eBay listing on Exhibit 2, there's a statement on the second page of the listing. "Item removed" -- it's right underneath the heading of what the unit is. "Item removed from a working environment and tested. All our equipment is tested, certified" -- something looks to be maybe cut off -- "with our biomedical technicians."
Do you know what testing or certification that would involve?
A. No, I do not.
Q. Have you ever bought equipment from an eBay listing for use in one of the hospitals that you were responsible for?

A. Oh, no.
Q. And have you ever instructed anyone else to do that?
A. No.
Q. Would you approve of it if someone else did?
A. I don't think so, unless there is a life-and-death situation and that's the only solution.
Q. You said something about the relative humidity and I wanted to be sure I understand what you were saying there. If I heard you correctly, you said that the relative humidity of a device while used on the floor would be greater.
Did I hear that right?
A. You did.
Q. Okay. Can you please tell me what you mean by that?
A. Sure. A device that is sitting about an inch, inch height from the floor, a floor that is subjected to cleaning agents and a variety of fluids, maybe fluids from patients, blood, et cetera, to have an air

intake so close to such an environment that the humidity, the relative humidity that was in the product can be increased compared to other area.
Q. Are you familiar with the various positions a Bair Hugger device may be used in in a hospital environment?
A. Yes.
Q. What are they?
A. According to the intended use, it's everywhere there is a patient.
Q. I'm sorry, my question may not have been clear. I was speaking about position on the floor versus position in some other way. Are you familiar with more than one potential way that a Bair Hugger device might be placed in an operating room?
A. Yes.
Q. What placements are you aware of?
A. Well, this particular model, the 750, has an IV clamp, and so I indicated in my report, and the purpose for this IV clamp is to place the product above the floor. So it could be on the IV clamp, it can be on the

floor. For all practical purposes, you can put it on the meal tray next to the patient. So there is no limit, actually, to where it might be.
Q. And it's your statement that the relative humidity within the device will be different depending on whether it's placed on the floor or an IV pole?
A. Correct.
Q. Have you ever measured the relative humidity inside the device in either location?
A. No, I did not.
Q. Have you ever measured the relative humidity of any air in an operating room?
A. Absolutely.
Q. In what conditions?
A. As part of my responsibility for operating room safety and air pollution control and isolation power. In specifically operating room, I would be measuring relative humidity, temperature, and the status of the electrical isolation panels in the operating room.
Q. Is there a standard for the

relative humidity and what it should be kept within in an operating room?
(Brief interruption.)
A. Sorry. I thought that... it is on vibrate.
MR. BANKSTON: That's weird.
MR. GOSS: Then it's a loud vibration.
THE WITNESS: Sorry about that, but it is on vibrate.
Back to your question, the operating room has a range for standard environment for relative humidity and for temperature controlled by National Fire Protection Association, NFPA 1990 standard, and by ASHRAE, American Society for Heating, Refrigeration and Air Conditioning, I think.
BY MS. EATON:
Q. Do you know what the humidity range is that's acceptable for an operating room?
A. No, I'll have to search it.
Q. And have you ever done any testing in an operating room that would demonstrate

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that the humidity reading by the floor is different from the humidity reading somewhere else?

A. I do not recall a specific study that I conducted about that. But since I was doing that frequently, I would change the altitude of -- or the height of the measuring device and it would show a higher humidity at the floor level.

Q. Can you tell me what any of the readings would be and give me a sense for how different one might be from the other?

A. No, I'm sorry. That was a very long time ago and very routine, almost weekly task, that I don't remember numbers.

Q. How long ago?

A. Probably late '70s, early '80s.

Q. And what kind of instrument were you using?

A. Hygrometer.

Q. Is the same type of instrument used today, do you know, as was used back then?

A. I believe so. It's very simple, taking a human hair and see how much it

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stretched in the presence of vapors.

Q. Okay. Are you able to give me any quantification at all of the difference at any height with -- either what the difference in height was, what the difference in temp- -- or humidity was, I'm sorry?

MR. BANKSTON: Objection, form.

A. I think we are marching towards an area of guessing. No, I cannot tell you. I can tell you simply that the device would be on the cart most of the time and sometimes I will take it and place it down on the floor just for my education.

BY MS. EATON:

Q. How high was the cart?

A. How high was the cart? I have no clue.

Q. Do you have any expertise in microbiology?

A. I do not.

Q. Do you think that the humidity of an environment makes a difference in the ability of bacteria to survive?

A. Yes, I do.

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Q. Based on what?

A. Based on studies that I read specifically for this case.

Q. Where will I find those in your report?

A. Oh, in many places. You can take Dr. Jarvis, a world expert in the area. You can take the microbiologist of 3M, Dr. Hall, specifically talking about it. There are ASHRAE standards that address that.

Q. I'll come back to that.

A. National Fire Protection Association, NFPA 1990, is another document. I was a member of that committee.

Q. When did you buy this -- when was this device purchased, do you know? I couldn't determine a year or a month on there.

A. I read here that it says delivery estimated between Monday, June 26 and Monday, July 10th.

Q. Yes, I did see that. I didn't know if you knew when it actually arrived or when you actually got it.

A. No, I don't remember.

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Q. You were retained in previous cases related to the Bair Hugger. Is that correct?

A. In singular, previous case, yes.

Q. You issued a report?

A. Yes.

Q. Did you ever examine a device before issuing that report?

A. I'll have to look at the report to refresh my memory.

Q. Do you have any memory of having examined a Bair Hugger device before this year, this -- the work that's reported in the report for this case?

A. I'll have to read that report, but as we sit here, no, I do not recall.

Q. If you would turn to Exhibit 2 again for a moment, I see two invoices attached, and I believe that my copy reflects the invoices that we were provided for your work. If you could please take a look at those two invoices and see if you believe there are any others.

(Document review by witness.)

A. No, I think there is a -- a more

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recent one was just issued.
BY MS. EATON:
Q. When was it issued?
A. Maybe 10 days ago, something like that, two weeks.
Q. Do you have a copy of it available?
A. No.
MS. EATON: Counsel, can you provide that?
MR. BANKSTON: Yeah, that's no problem.
BY MS. EATON:
Q. Does the issue that was just -- I'm sorry. Does the invoice issued 10 days or two weeks ago include your time -- all time from February 2017 through today?
A. No.
Q. Or through the time it was issued? I'm sorry.
A. That's correct.
Q. Okay. So those three invoices taken together will reflect your work on this case plus whatever has come since?
A. That would be a true statement.

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Q. Do you have a sense for how many hours are on the invoice that was last issued?
A. I was going to say about 30 hours.
Q. Since that invoice was issued -- I'm sorry, and what was that -- I apologize.
What was that time spent on, just categorically, what kind of work?
A. Basically preparation for deposition.
Q. In the last 10 or 14 days since the close of the previous invoice, how much time have you spent?
A. I did not review that.
Q. I'm sorry, maybe we're not communicating.
What was the time period that the last invoice closed with, what month or...
A. I don't remember.
Q. Okay. In July 2017, have you spent any time on this matter?
A. Yes.
Q. Is that included in any invoice?
A. No.
Q. Okay. How much time in July 2017

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have you spent?
A. I didn't aggregate that.
Q. Do you have any sense?
A. No.
Q. Did you spend any time preparing for this deposition in July 2017?
A. Yes.
Q. What did you do?
A. I re-read depositions of other defendant officers, of other experts. I reviewed literature studies. I read my report. I read Mr. Ulatowski's report. That's about it.
Q. What depositions did you review in July 2017?
A. I believe I went over all of them.
Q. All of the ones you had been provided?
A. Yes.
Q. You said something about experts. What expert depositions have you been provided?
A. You want me to chant it from memory? It's in my report.

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Q. Okay. Let's go ahead and have your report in front of you. That's Exhibit 3.
(David Exhibit 3 marked.)
MS. EATON: Do you need a copy?
MR. BANKSTON: Oh, no, I'm fine.
BY MS. EATON:
Q. If you would turn to page 46 of Exhibit 3 -- first of all, I'm sorry, sir, is Exhibit 3 your report? Does it appear to be?
A. Yes.
Q. And if you would look at page 45, is that your signature?
A. Yes.
Q. And page 46 begins a section titled "Materials Reviewed." Is that correct?
A. That is correct.
Q. And if I go through that, I don't see any expert depositions listed. Am I missing something?
A. You're missing looking at page 49.
Q. Okay. This is expert reports, and I'm sorry, I'm not interpreting that to mean depositions. Do you mean that you've read transcripts of depositions or have you read

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reports?
A. Reports.
Q. Have you read the transcript of the deposition of any expert witness for either plaintiffs or defendants?
A. I think I read Mr. Tim -- I don't want to mispronounce his name --
Q. Ulatowski?
A. Thank you, Ulatowski.
Q. His report or his deposition?
A. I think his deposition.
Q. Did you ever review his report?
A. Yes.
Q. Are there any other -- I don't believe that that's listed in your materials reviewed. Do you believe I'm mistaken about that?
A. Everything I reviewed is in the box that I brought with me here, so if it's in the box, I reviewed it.
Q. Okay. I'll take a look at that at a break.
Do you believe that there are any other plaintiff or defense expert witness

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reports that are not listed on page 49 of your report that you have reviewed?
A. No.
Q. I'm just waiting for you to get there.
A. No.
Q. If you would look at page 46 of your report, there's some depositions listed. Did you read each of these depositions in total?
A. Yes.
Q. Okay. Any other depositions that you believe you've read beyond these listed and Mr. Ulatowski's?
A. No. That would be it.
Q. If we would look at Exhibit 2, I want to look at the invoices for a moment.
Actually, first, I'm sorry, the very first item attached to this response is an expert witness retention contract. Within Exhibit 2, after the pleading part, there is an expert witness retention contract.
A. Yes.
Q. Is this your signature?

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A. Correct.
Q. And is this related to the report that we have in front of us as Exhibit 3?
A. Correct.
Q. Okay. Dated October 15 of 2016?
A. It does.
Q. Was this when you were retained for your work in this case?
A. I believe I was retained prior to that. I'm trying to think. We may not have that contract in place at the time.
Q. If you would look at the first invoice, was the July 2016 meeting in person or by telephone?
A. I do not recall.
Q. Do you recall who you met with?
A. No.
Q. Do you recall if anyone was present that you did not believe to be an attorney?
A. No. It's specifically a meeting with an attorney.
Q. Who contacted you originally to retain you for Bair Hugger litigation in the first case?

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A. I believe Mr. Bankston.
Q. Do you know Mr. Bankston from before that contact?
A. We have a professional association on another case.
Q. What case is that?
A. It should be on my case list.
Q. Are you able to point me to which one if you use Exhibit 3?
(Document review by witness.)
A. There's no list here.
BY MS. EATON:
Q. I believe between the report and your CV, tucked in there is a list. I don't think it's numbered by page or I would refer you to it.
A. Oh, I see. On the second page, the fourth one from the top, Kaster, Lynch, Farrar & Ball, which is a light therapy.
Q. Is that the only other time you have worked for a client that was represented by Mr. Bankston?
A. Correct.
Q. When did that -- 2014 is the year

listed here.
A. Yeah.
Q. Is that the year of testimony or the year of all of your work?
Let me ask a better question. When were you retained in that case?
A. It says 2014.
Q. That's -- your understanding is that the year listed in this chart is the year you were retained for a case?
A. The year that I provided professional services.
Q. Did you prepare this list?
A. Yes.
Q. What is Biomedical Engineering Consultants LLC?
A. This is a business that I'm operated under.
Q. Are you the only person who works in that business?
A. Correct.
Q. What do you do in that business, other than -- I'm sorry, let me ask a different question.

Does that business involve any work other than litigation consulting?
A. Yes.
Q. What else do you do?
A. I provide biomedical engineering services to healthcare providers, meaning to hospitals that would like to improve their medical technology management program. I provide professional services to manufacturers of medical devices that would like to start or improve their field biomedical services.
Q. Field?
A. Correct.
Q. Do you mean servicing devices in the field?
A. Correct.
Q. Okay.
A. I provide regulatory services to startup companies in the medical device field.
Q. What does that mean, "regulatory services"?
A. Advise them on how to be ready for 510(k) submission and the appropriate information to be included in such. And

finally, I am -- develop and implement telemedicine programs.
Q. For the regulatory advice that you provide, is it advice about the -- I would like more detail about that. What aspect of a 510(k) submission is it that you're advising people about?
A. Sure. I'll be happy to help you with that. The 510(k) submission has a process that is looking for how to classify the device, how to identify a predicate device, what is the substantial equivalency criteria that one can use, and specifically to include studies and testing in a way that supports the submission.
Q. What training or education did you have that allows you to do that work, or that you draw upon when you do that work?
A. Sure. I've been working in the biomedical devices field for four decades and use my expertise to understand how a device works safely and what risk is associated with them, seeing it from the clinical side.
I have obtained education and

training throughout my career and have been working with a consultant to the Food and Drug Administration on several panels and have been trained by the Food and Drug Administration to fulfill that role. And I recently have been asked to become a regulatory advisor to the Innovation Institute of the Texas Medical Center based on my experience and training.
Q. What regulatory training -- you mentioned training, I think, regulatory training. What regulatory training have you had? Has it been part of any formal program that you can identify?
A. At the master level when I was at the university pursuing my degree, I took a regulatory course that was taught by a biomedical engineering professor. I continued at the doctorate level to obtain training in the field. I think it was a nurse who taught the course at the doctorate level, but regulatory principles. And I continuously attend the annual meeting of biomedical product and instrumentation and take a seminar and lectures as well as reading books that are

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published as well as contributing to regulatory books myself. So I'm doing research to write my chapter for that.

Q. Okay. That's something ongoing right now?

A. No. That has been submitted, complete. The book has been published, I think end of last year.

Q. Is that on your CV?

A. Yes.

Q. Can you show me which one you're referring to? If you know the title off the top of your head, you can just tell me.

(Document review by witness.)

A. It looks like we don't have the recent year here on the copy I'm holding.

BY MS. EATON:

Q. Do you know the title of the book?

A. No.

Q. Are you able to provide me with an updated CV?

A. Sure.

Q. What was your chapter about?

A. I don't remember the title. It was

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about risk processes of medical devices subject to regulation.

Q. Of the regulation? What regulation?

A. Global medical device regulations. FDA, EU, others.

MR. BANKSTON: Is now a good time for a bathroom break? Should we do that?

MS. EATON: Sure.

THE VIDEOGRAPHER: We are going off the record at 10:42.

(Recess, 10:42 a.m. to 10:57 a.m.)

THE VIDEOGRAPHER: We are back on the record at 10:57.

BY MS. EATON:

Q. Dr. David, how many times have you met with attorneys that you understand to represent the plaintiffs in this Bair Hugger litigation, in person?

A. I don't keep count. Whatever is in my invoices, that would reflect it.

MS. EATON: And to be clear, I was hoping to get the remaining invoice

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before we're off the record today. I would like to receive it --

MR. BANKSTON: Yeah, sure.

MS. EATON: -- during the deposition.

BY MS. EATON:

Q. Every time that it says "meet with attorneys" here, is it a personal meeting?

A. Correct.

Q. Which attorneys have you personally met with, individuals?

A. I'm unable to rehearse that.

Q. Is there anyone whose name you recall that you met with?

A. Except those who are present here, no.

Q. Do you believe you have met with any other attorneys besides Mr. Bankston and Mr. Hodges?

A. Yes.

Q. How many other people?

A. I don't recall.

Q. Do you recall if they were men or women?

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A. I believe they were men.

Q. Do you recall how many times you had a meeting where someone other than Mr. Bankston or Mr. Hodges was there?

A. No.

Q. Do you believe any of your meetings with attorneys also involved any people who you did not believe to be attorneys?

A. No.

Q. Did you meet with anyone to prepare for this deposition?

A. With Mr. Bankston.

Q. Just him?

A. Yeah.

Q. When was that?

A. That was yesterday.

Q. For how long did you meet?

A. Four hours.

Q. Any other meeting that you, in your mind, associate with preparing for the deposition?

A. No.

Q. Have you met with any attorneys since you prepared your report?

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A. Can you repeat the question?
Q. Have you met with any attorneys since you prepared your report?
A. I meet with attorneys all the time.
Q. Related to your work in this case.
A. Mostly with Mark.
Q. And have you met with him since you prepared your report, do you believe, other than yesterday?
A. Yes.
Q. Related to your work on the Bair Hugger litigation?
A. Correct.
Q. Do you recall how many times?
A. No.
Q. What percentage of the time of your business, Biomedical Engineering Consultants LLC, is spent on litigation-related work in the last five years?
A. My business in totality has the activity we described earlier this morning.
Q. Right.
A. Which is more than the litigation,

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and I don't keep separate accounts.
Q. Do you have any sense? Is it more than 50% on litigation?
A. I'll have to review five years of tax returns, but -- I don't know, might be correct.
Q. Well, what about 2017? What percentage of your work activities in 2017 have been related to litigation-related work?
A. I don't believe, Counsel, that I keep separate revenue stream in separate accounts, so it's very difficult for me to answer your question. It will be just a guessing game.
Q. Well, let me see if I can -- what -- is your consulting rate the same -- let me start over with a clean question.
Is your consulting rate the same for any of the kinds of work that you do?
A. Yeah. I might have different terms. For example, I am a consultant for a very known and large medical center in the Silicon Valley that required me to actually spend physical time there for a while, and my

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rate was changed because the duration of the project was long. So, yes, the rate is changing.
Q. Depending on the work?
A. Correct.
Q. Okay. Set aside revenue streams for a moment. I'm asking how you've spent your time in 2017. Do you have a sense for what percentage of the time you've spent in 2017 has been related to litigation work?
A. No.
Q. More or less than 50%?
A. I don't know.
Q. Do you know if it's more than 75%?
A. Definitely not.
Q. For 2016, do you know if the amount of time that you spent on litigation-related work was more or less than 50%?
A. That might be a good guess.
Q. Well, I said more or less. Are you saying it's about half in 2016?
MR. BANKSTON: I object to the form.
A. I'm guessing. I don't know.

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BY MS. EATON:
Q. Do you believe it was more than 50% in 2016?
A. I don't think so.
Q. Do you believe it was more than 25%?
A. Now I'm guessing. So if you want me to guess, I would say more than 25%.
Q. Well, I'm just asking for your best estimate of how you spent your time last year.
MR. BANKSTON: Object to the form.
A. I wish I could answer that. I do not keep booking records the way that you asked the question. My business in totality is what I enjoy doing, and those categories we described already have industry, academia, healthcare providers, litigation, telemedicine. I have both domestic and international projects in these categories.
BY MS. EATON:
Q. Has the amount of time -- I'm sorry. Has the percentage of time that you spend on litigation-related work changed over the last five years?

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A. It is changing year to year.

Q. Has it been in a trendline of a certain direction, or does it vary?

A. No. It just varies. It -- as I said, when I have a project like the Silicon Valley that would have long duration involvement with the medical center, naturally I'll have less time for other activities, so it's varied.

Q. When was that project?

A. That was 2016.

Q. Are you able to identify the center?

A. I'll have to see if I have any confidentiality agreement.

Q. What was the work you were doing for that center?

A. They are in the process of building adult and pediatric hospitals, new facilities, and wanted to make sure that they are ready, as far as their medical technology management program, for the challenge.

Q. You're helping them to design their program or reviewing a program -- I'm sorry,

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let me -- what was your role in that?

A. I reviewed the existing program and redesigned the program to meet the new challenges.

Q. What posed the new challenges?

A. As I said, the construction of two new facilities, the large amount of new technologies that would come to those facilities.

Q. Was your focus on the process by which they review medical technologies?

A. The process was part of it. Also, the ability to address deliverables as far as quantifying patient outcome relating to technology.

Q. Was there a specific rubric or criteria for that addressing patient outcome?

A. No. It depends on the environment. Outpatient clinic versus trauma versus pediatric floor.

Q. I'm just wondering if there was a specific rubric that you used, a specific set of criteria or standards?

MR. BANKSTON: Object to the form.

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A. The review was very elaborate, so yes, there was a certain criteria, but for the different steps there was different criterias.

BY MS. EATON:

Q. Did your work involve evaluating specific medical technologies?

A. No.

Q. For November 2016, if you would turn to the invoice in Exhibit 2, do you know how much of this eight hours was meeting with an attorney?

A. Obviously it was less than eight because there are two other activities involved in that eight hours. How much less, I don't know.

Q. Do you have a specific recollection that reviewing material and scientific literature is a separate task from meeting with the attorney?

A. Yes.

Q. Do you know what materials or literature you were reviewing in November 2016?

A. No.

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Q. In December 2016, "Review material on-line vendors," what does that mean?

A. That means that I search and review material associated with vendors with the use of computerized technology. I went online and looked at the information.

Q. I don't -- what computerized technology? Vendors of what?

A. Vendors of warming devices, patient warming devices.

Q. Do you know what vendors you looked online for?

A. No.

Q. What was your purpose for looking at vendors of patient warming devices?

A. To identify products that are offered on the market, to identify a spectrum of features, and any marketing material that they have.

Q. Did you do the searching?

A. Yes. I'm charging for my time, yes.

Q. Well, you're charging specifically -- the entry says "Review

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material, online vendors," right?
A. Yes.
Q. Okay. Did you review material that was provided to you?
A. No. Let me try to explain it so it will be clear. When I write on an invoice "Review material online," that means I went with search engines on the internet and looked at material. In this case, it says "vendors," so I looked for vendors and products associated with heating patient technology.
Q. What search engine did you use?
A. I usually use the Google and the Firefox.
Q. Do you recall which search terms you used to identify other patient warming devices?
A. No.
Q. Did you have any criteria for what kind of devices you were looking for?
A. I probably have things in my mind and that's why I went to look to see if there's answers there. But as I sit here today, no, I cannot tell you words or key

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phrases that I put in.
Q. Did you choose to examine materials for every patient warming device you located with this search?
A. Correct.
Q. Did you document in your report every patient warming device that you located with this search?
A. No. I didn't see a need for that.
Q. How did you select which ones you included in your report and which ones you did not?
A. Those devices that have similar intended for use, devices that are marketed for similar environments of use, and devices that have a similar principle of conduction or convection heat. There are others that would have radiation heat, and I didn't use those.
Q. Did you document in your report -- okay, I'm sorry.
You said you reviewed materials for all the ones that were located with your search and you documented in your report those that you considered relevant. Is that right?

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A. That would be a fair statement.
Q. Do you recall which ones you saw and reviewed materials for and did not document in your report?
A. There were -- an example will be infant warming devices that use infrared heating elements.
Q. Okay. That would be radiant heat?
A. Correct.
There are forced-air devices used in a very specific environment like Isolette that I'm very familiar with, working at Texas Children's Hospital, did not include.
Q. Anything else that comes to mind?
A. No. Those are examples.
Q. Did your search return the HotDog warming device?
A. Sure.
Q. Why is that not in your report?
A. I picked up a similar device.
Q. Why is the HotDog device not in your report?
MR. BANKSTON: Object to the form.
A. Because I took a similar device

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that used the same principle.
BY MS. EATON:
Q. Which --
A. -- when -- and same features and put it in the list of devices.
Q. Which device is that?
A. I'll have to look at my report. I believe it's the VitaHEAT, V-I-T-A-H-E-A-T. And by the way, I see that on these invoices, the first entry is July 2016 and you asked me about the retainer agreement from October. And it shows you that I was working before that agreement was signed.
Q. I didn't say that you were working. I had asked if you thought you were retained for the case before you began. Were you retained for the case during that initial meeting --
A. Yes.
Q. -- in July?
A. Yes.
Q. How many other warming devices had similar intended uses, marketed for similar environments of use, and a similar principle

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of conduction or convection that you did not choose to include in your report?

A. None.

Q. The HotDog was the only one you left out?

A. Yeah.

Q. Did you look at materials about the HotDog?

A. Yes.

Q. What kinds of materials did you look at about the HotDog?

A. I looked at the description, at the 510(k) submission, at YouTube video.

Q. How did you obtain the 510(k) submission for the HotDog?

A. I think a summary document that was available online.

Q. So you looked at the 510(k) summary or you the looked at the entire 5- -- let me ask that differently.

Do you believe that what you looked at was the entire 510(k) submission?

A. I take your correction. Summary, yes.

Y. DAVID

Q. It was what was available online?

A. Yes.

Q. Do you -- did you -- I'm sorry. Did you print out any materials related to the HotDog?

A. No.

Q. Did you save any PDFs or download any materials related to the HotDog?

A. I don't believe so.

Q. Was the review of those materials, did that occur in December 2016 in connection with your review of other products?

A. That would be a fair statement.

Q. Will I find on your materials reviewed list any indication that you looked at materials about the HotDog? If you would look at Exhibit 3, I don't see anything, but I want to make sure that I'm not missing something.

(Document review by witness.)

A. No, I don't see a reference to it.

BY MS. EATON:

Q. Could you please turn specifically to page 46? I interpret pages 46 to 51 of

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your report to be a listing of the materials you reviewed. Is that correct? In connection with your work in this case. Is that what this is?

(Document review by witness.)

A. Yes.

BY MS. EATON:

Q. Who prepared this list?

A. Who prepared the list?

Q. Yes.

A. I did it. I don't think that I typed those numbers on page 47. That's -- probably a clerk did it for me, but...

Q. Are there other materials you reviewed in connection with your work in this case that we should add to this list?

A. No.

Q. Did you make an assessment that the VitaHEAT product and the HotDog product are the same?

MR. BANKSTON: Object to the form.

A. The same principle of warming patient, yes.

--oOo--

Y. DAVID

BY MS. EATON:

Q. Did you make a comparative assessment of their efficacy or safety?

A. No.

Q. In December 2016, there is a reference to FDA, just by itself. Do you know what that means?

A. That means that continuing with the review material online. It was the vendor's website and FDA database.

Q. For the 510(k) summaries?

A. Yes.

Q. Or for something else in addition? I'm sorry, that was a bad question. Was the only purpose for which you looked at the FDA website to obtain the 510(k) summaries on this?

A. Yeah, I think so.

Q. There's also an entry for "examine product."

Does that mean the Bair Hugger device that you obtained for your work in this case?

A. Correct.

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Q. I'd like to talk about that examination for a moment. There are entries on December -- I'm sorry, in December 2016 for "examine product."

In January 2017, there's a reference to "device testing and photography," and in February 2017 there's a reference to "device examination." I want to get a sense for your work with the actual Bair Hugger device. How many times did you do work, review, inspection, testing, anything, with that device related to your work in this case?

A. I believe the invoices are reflecting correctly that I have activities in December, January, February.

Q. Do you believe that when we receive the next invoice, that will show continued work with the product? Or do you believe this was it?

A. I believe that's it.

Q. Exhibit 3 contains some photographs of the device you examined, correct?

A. Correct.

Q. How many photographs did you take?

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A. I don't have a list. I provided the photography results to counsel and incorporated in my report the one that I felt would explain my opinions.

Q. Do you have any sense for how many photographs you took?

A. No.

Q. Were they taken -- on what kind of a device?

A. I believe it is a Pentax camera.

Q. Were they digital photographs?

A. Yes.

Q. Did you delete any of the digital photographs you took?

A. No.

Q. Do you still have the original media that the photographs were taken onto, the chip?

A. I have the chip, but it was erased and used for other purposes.

Q. So you don't have the original photographs anymore?

MR. BANKSTON: Object to the form.

A. The original photographs would be

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saved to my server, and then I used the chip again.

BY MS. EATON:

Q. Okay. Do you have all of the photographs you ever took of this device or in connection with your work with this device on the server?

A. Yes.

Q. Okay. On -- let's take a look at the Exhibit 2. Actually, no, Exhibit 2 is not going to help us.

(Sotto voce discussion.)

BY MS. EATON:

Q. I marked the subpoena as Exhibit 1. Is that correct?

A. Yes.

Q. Let's take a look at Exhibit 1. If we look at Exhibit A, the first entry asks for documents reviewed in anticipation or preparation for the deposition. Have you told me earlier all of those that you can recall?

A. Yes, I did.

Q. The second item asks for correspondence and deponent's exchange between

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you and non-lawyers with information related to your work in this case. Was there any such correspondence or document exchange between you and someone that was not a lawyer?

A. No.

Q. Category number 3, any notes related to work in this matter, whether handwritten or typed; are there any such documents?

A. No.

Q. Category 4 are copies of documents provided to you by plaintiffs' counsel on which you have made notations, highlighting or underlining. Have you brought all of those to the room today with you?

A. Correct.

Q. Do you receive documents from -- have you received any documents from plaintiffs' counsel?

A. Yes.

Q. Have you received those -- in what format?

A. Hard copy.

Q. Have you ever received documents

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electronically from plaintiffs' counsel?
A. If I did, I requested hard copy.
Q. The ones you reviewed came in hard copy?
A. Correct.
Q. Have you brought -- in this box that's sitting at my feet today, you've brought all the hard copies you received?
A. Correct.
Q. And if you made any notations or highlighting, I take it, then you would be making that on a hard copy as opposed to some electronic media?
A. Correct.
Q. Do you have a current impression about what items you may use as demonstrations, exhibits or aids in the course of your testimony?
A. I have not discussed that with counsel, and I'm not aware that I'm providing testimony. He needs to advise me of that. Then I will think about what do I need to use.
Q. If we look at category 6, does your CV, as of the time it was prepared, include

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all of the books, treatises and articles that you have authored or co-authored up to that time?
A. Correct.
Q. Will you be able to provide me with a current CV that includes an update of everything that you've authored through now?
A. Yes.
Q. Do you have any written correspondence with anyone other than counsel related to your work in this case?
A. No.
Q. If you'd look at item number 17, do you have any written communications, including e-mails, between any of the individuals listed here?
A. No, I do not.
Q. Have you ever spoken with any of those people by telephone?
A. I did not.
Q. What about Scott Augustine? Have you ever spoken with him?
A. No.
Q. Have you ever exchanged any writing

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with Scott Augustine?
A. No.
Q. Have you ever spoken with Randy Benham?
A. Who is Randy Benham?
Q. Well, first, let me ask if you recognize the name.
A. I do not.
Q. Okay. Randy Benham is an attorney at -- I believe he's an attorney for Scott Augustine or his entities.
A. I see. No.
Q. Does that context --
A. No.
Q. -- change your memory?
A. No.
Q. You don't believe you've ever exchanged writings with him?
A. Correct.
Q. Okay. In 20, there's a listing of some individuals who have the last name Augustine. Do you believe you've ever spoken to any of those people?
A. None of those.

Y. DAVID

Q. Do you believe you've ever exchanged any communication with any of those people?
A. No, I did not.
Q. Okay. Item 21 asks for any study, test, trial, experiment, research or data that -- item 21 is a long question designed to get at any testing that you've done on a Bair Hugger device. I will use that shorthand for what actually appears in item 21.
If you would look at the literal words of item 21 and please tell me if there's anything beyond what has been disclosed in your report that would fit that description.
(Document review by witness.)
A. No, nothing comes to mind.
BY MS. EATON:
Q. Do you have any documents responsive to category number 22?
A. No, I don't have any of those.
(David Exhibit 4 marked.)
BY MS. EATON:
Q. I've marked as Exhibit 4 a collection of additional photographs that were

Y. DAVID

not contained in your report. Well, I'm sorry, let me say that differently.

I requested that we receive any photographs you had taken, whether or not they were contained in your report, and I received the items that are copied in Exhibit 4. Are those photographs of the device that you examined in connection for your work in this case?

(Document review by witness.)

A. Yes.

BY MS. EATON:

Q. Did you take all of the photographs that are in Exhibit 4?

A. Yes, I did.

Q. I counted 11. If you would, please, double-check me.

A. Oh, they're two-sided.

Q. Yes.

A. I didn't know. You are correct.

Q. Do you believe that those 11 photographs, in addition to the ones that were selected for your report, reflect all the photographs you ever took of this device?

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A. I believe so.

Q. Since receiving or reviewing the subpoena that -- or actually, let me just ask that differently. Would you be willing to double-check your server to see for me if there's any other photographs there that are not contained in your report and in Exhibit 4?

A. Will I have a copy of that to compare?

Q. Would you be willing to check your server to see, yes, if Exhibit 4 and your report contain all of the photographs that you took?

A. Yes, I'm willing to do that.

Q. I would request that you do that and inform your -- the plaintiffs' counsel if there's anything that you find that is not collected here. Is that something you could do?

A. Yes. The logistic issue is that I need a copy of those to compare.

Q. Sure. When we're done today, I can give you my copy.

A. Okay.

Y. DAVID

Q. You can take it with you.

Taking for a moment Exhibit 4 and the photographs contained in Exhibit 4, had you done anything to the device at all other than take it out of the box and open it before these photographs were taken?

A. When you say "open it," I disassembled. I mean, that's what you're asking me?

Q. Yes.

A. I disassembled it.

Q. Yes.

A. Yes.

Q. Had you done anything else with the device before you took the photographs?

A. Probably wiped the outside. I don't think much more than that.

Q. Let me -- let's specifically go to the fourth photograph. You know what? And maybe -- would you take a moment and just use a pen and write -- if you would write a 1 on the first -- just in the little white spot on the bottom of the first page of Exhibit 4 -- I'll do it at a break. I'll write pages. But

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if you could start with Exhibit -- or with page number 1 of Exhibit 4.

A. Okay.

Q. Had you done anything to the device at this time other than unscrew the cover and remove it? Or the base, I'm sorry, the base, and open it up to be able to take this picture?

A. Before I took this picture, I probably removed the filter and then got to the point where I'm taking this picture.

Q. So by "the filter," do you mean the corrugated rectangle that we see in the blue base that's --

A. Correct.

Q. -- depicted here? You had already taken the filter out and put it back in?

A. Correct.

Q. Is there any photograph, either in your report or in this collection, that shows the device before you took out the filter? Do you know?

A. The photographs in my report are showing --

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Q. The one that shows you with the box on page 11?
A. On page 11 and page 12.
Q. Okay. Who took the photograph on page 11?
A. Myself.
Q. You took the photograph of yourself?
A. Yes.
Q. How does that work?
A. You put it on timer.
Q. Was anyone present when you opened the box and took the device out?
A. No, I put it on a tripod with a timer and took a picture.
Q. I'm sorry. Separate from the issue of the photograph, was anyone present when you opened the box and took the device out besides yourself?
A. No.
Q. Okay. And your belief is that the photograph depicted on page 12 also is taken right after you had taken the device out of the box?

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A. Yes.
Q. Did you take that photograph -- any other photographs here, in either your report or Exhibit 4, that were taken during that initial time when you opened the box, took the device out, and before you had done anything at all to the device?
A. No. That's it.
Q. If you look on page 12, when you say, "When I opened the air intake and removed the air filter," how would -- did you take off the two screws that are depicted here in the photograph on page 12 or is there something else that you did?
A. No. On the black part, the two screws.
Q. On the sort of rounded parts of the -- the rounded parts of the black grate, those screws that are apparent in the photograph, you took those off?
A. The semicircle, yes.
Q. Okay. You said, "It was immediately obvious that dust particles were present on the filter and the blades of the

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fan behind it."
Is there any photograph depicting what you saw when you first opened the air intake?
A. This series of photographs were taken in sequence, so those are all -- come after that.
Q. Are you referring to the ones contained in Exhibit 3 in your report, or are you referring also to the ones in Exhibit 4?
A. In my report, there are more than on just that occasion. Like on page 14, they're taken different time. But page 11, 12 --
Q. 13?
A. -- and 13 were taken the same time, and then I think I came back and took what you marked as Exhibit 4.
Q. Okay. Let me be real clear just to get this sorted out. 11, 12 and 13 you believe were taken at the same time.
A. Correct.
Q. 14 was taken on a different day?
A. Correct.

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Q. What about the photographs that appear on pages 15 and 16? Do you know if those were taken --
A. 15 and 16's were taken when Exhibit 4 was -- the rest of the pictures in Exhibit 4.
Q. And is that a different occasion than those on pages 11, 12 and 13?
A. Correct.
Q. Okay. Do -- let's go to the photograph on the first page of Exhibit 4. Does the filter in this photograph, was it changed at all by your handling of it? Did you do anything that would change the appearance of the filter?
A. No.
Q. And then what about the motor and blades that we can see on this page? Did anything you do change the appearance of that?
A. No.
Q. Did you take any picture of the filter as it appeared when you first opened the cover? The base, I'm sorry, the base.
A. I do not recall.

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Q. Did you do any method of quantification of the dust particles that were present?

A. That was not my objective.

Q. Did you do any quantification of the dust particles that were present?

MR. BANKSTON: Objection to the form.

A. My objective for the examination was to understand the physical configuration and how the device integrated different components. I was not set to do a specific quantification of one parameter or another.

BY MS. EATON:

Q. I appreciate that information, sir, but I really -- and I can infer from your answer that you didn't do anything, but I actually do want a clear answer on the record so we are communicating.

Did you do anything to quantify the dust that you found?

MR. BANKSTON: Objection to form.

A. Besides visually look at it, no, I did not.

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BY MS. EATON:

Q. Did you take any sample and have it cultured to see what the dust was or what was in the dust?

A. Not my aim.

Q. And did you do it?

MR. BANKSTON: Object to the form.

A. I didn't see a reason to do it.

BY MS. EATON:

Q. Okay. I will infer from that answer that you didn't do it, and please correct me if I'm wrong about that.

MR. BANKSTON: Object to the form.

A. You're correct.

BY MS. EATON:

Q. Thank you. During your -- well, let me hold that for later.

Is there any photograph that would depict dust on the blades of the fan?

A. I don't think that I tried to document that.

Q. There's a reference on page 12 to a "dark and warm cavity." Did you actually take a temperature of the inside of the device at

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any time?

A. No, I did not.

Q. What do you mean by the word "warm"? What temperature range do you have in mind?

A. Higher than the surrounding environment.

Q. Do you have any knowledge from your work in this case about what is the temperature inside a Bair Hugger device when it is operating?

A. It will be above the room temperature because you have a magnificent-sized heating element sitting there and you can see the block of this electronic component in the center of the box. The enclosure is tightly around this heating element, so inside the box will be a higher temperature than in the surrounding room.

Q. And do you have any sense for what that temperature will actually be?

A. No.

Q. What does the photographs on page 14 depict?

Y. DAVID

A. I believe that when I examined the device, that a layperson will not have a good comprehension of what does it mean for the principle of the device function that air needs to come from below the device and get into the heating element and push to the blanket around the surgical site.

So on page 14, I grossly simulated the function of air being vacuumed in or sucked into the enclosure by the function of the fan behind the filter. And those are the pictures explaining to a layperson. It's very simply if there is something next to the intake at the floor level, it will be sucked into the enclosure.

Q. Did you -- where -- if I look at the top picture on page 14, there's some scraps -- is this paper? Are these scraps of paper?

A. Correct.

Q. Did you set the Bair Hugger device down directly on top of those scraps of paper?

A. And so it said under the picture paper cuts are placed next to the bottom of

the Bair Hugger side. So you can see that it was placed just where the paper are sucked in on the side of the enclosure.

Q. For purposes of the photograph you've held the Bair Hugger in an elevated position, right?

A. Correct.

Q. Okay. What I'm trying to figure out is: When you actually turned it on, where were the feet?

A. Sure, absolutely. The top picture is showing you the elements involved in the simulation; the Bair Hugger, the blue enclosure on the left and the pieces of paper cuts, white, on the right against black background. Then I put the Bair Hugger over those paper cuts, that they were such that I could see from the side of the enclosure how many of those are covered by the fan area and turned the Bair Hugger unit on. Then I lifted it and took a picture.

Q. Okay. So when you lowered the feet of the Bair Hugger device, did the device sit on top of any of the pieces of paper?

A. Yes.

Q. Did it sit on top of all the pieces of paper?

A. No. The bottom picture is showing you a piece of paper with the identification of T2.

Q. Yes.

A. Those few pieces were at the right-hand side in the top picture, those three pieces of paper on the right side. So the Bair Hugger was placed over the rest of the papers.

Q. Are you able to take a pen, and on Exhibit 3, outline roughly with either four corners or a box which papers -- where the device would have been sitting or which papers were covered by the device?

A. Uh-huh. I'm going to mark it on page 14.

Q. Yes, please.

A. But I don't want to confuse anybody looking at it, that that's not where the Bair Hugger was turned on. The papers were moved on the white surface.

Q. Okay. I'm sorry, then. Back up. When you turned the device on, where were the papers?

A. On the white surface.

Q. Okay. When you turned the device on, were the papers underneath the Bair Hugger device?

A. In the same form you see it on the black.

Q. Okay. So you took a picture on the black and then you physically moved the papers onto the white?

A. Correct.

Q. And then you set the Bair Hugger back down on the white part on top of the papers?

A. And as I said before, with the three right-hand-side paper cuts outside the filter area.

Q. Okay. Then no need to mark on Exhibit 3 at this moment.

When you say "outside the filter area," were those three paper marks by the T2, the three pieces of paper, were they still

within the base of the Bair Hugger device, beneath the base of the Bair Hugger device?

A. I think that I mentioned that I could see it.

Q. Yeah.

A. When the device was on top of the paper cuts, I could see those three outside.

Q. Okay. But within the white board that is depicted here on page 14?

A. Correct.

Q. Okay. What setting did you turn the Bair Hugger on to?

A. I used the three-temperature setting, and for this particular picture, I believe it was the high temperature.

Q. High temperature? Is there a fan -- is there a different fan speed? Or is there only one option for fan speed?

A. I'm aware of one option.

Q. Okay. Did you do anything to measure the air flow?

A. No.

Q. Okay. What kind of a room was this?

Y. DAVID

A. This was a biomedical laboratory.

Q. Okay. Is this laboratory designed to represent an operating room environment?

A. I'm glad that you're asking this question, because once again, I want to make it clear that I did not attempt to look at the device performance or features. I did not need to simulate the environment where its function. Once again, I wanted to see and acquaint myself with the device operation and integration of different components and the air flow through it.

Q. Was the laboratory designed to represent an operating room condition?

MR. BANKSTON: Object to the form.

A. I'm not that familiar with the lab, and I don't know if it was designed for it or not.

BY MS. EATON:

Q. Do you know if it did reflect operating room conditions?

A. Probably did not.

Q. Do you know anything about the air flow into the laboratory?

Y. DAVID

A. No.

Q. Do you know what the temperature was in the laboratory when you performed the operation that's depicted on page 14?

A. Yes. I took the room temperature.

Q. What was the room temperature?

A. It was exactly as the air-conditioning scale showed, and it was 74 degrees, I believe.

Q. Fahrenheit?

A. Correct.

Q. Is that the temperature of an operating room during surgery?

A. Probably not.

Q. Did you intend for this exercise depicted on page 14 to represent the conditions during clinical use of a Bair Hugger device during a surgery?

A. I might not be communicating clearly enough, so let me try again. My examination was not for clinical performance, was not intended on determining the features and the performance of the Bair Hugger 750 in a clinical environment or in an operating room

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or in any area that patients are cared for.

My examination was specifically for acquainting myself with the product elements, with the physical characteristics of how it is functioning, and with understanding the relationship between air intake, air outtake, how the accessories are connected, and that's the extent of it. So we keep coming back to questions about operating temperatures and the lab that is designed to be operating room, and I want to make it clear that if I'm not communicating that issue, I will try it a different way.

But it is a completely different purpose, and knowing that the device has multiple fault codes associated with it, it would be naïve to even try to do that features determination and clinical performance on such condition of the device. So it's further from my goals and objective as can be.

Q. So if we were to show this photograph, for example, these photographs on page 14 to a lay jury, would it be important for them to have that in mind, all that you

Y. DAVID

just said?

A. Absolutely.

Q. Did any of the pieces of paper get through the intake?

A. No, they did not. The intake spaces of the levers -- I hope I'm identifying it correctly -- but the black cover over the filter has smaller gaps than the size of the paper and the paper cannot penetrate the plastic container that holds the filter in place.

Q. So if we looked at page 12 of Exhibit 3, is that the grate that you're speaking about?

A. Thank you. Very good. Yes.

Q. Okay. So that grate was in place when -- was in place when the exercise was done that's depicted on page 14?

A. Correct.

Q. And all of the paper was stopped by it?

A. Yes.

Q. Did you ever do any test with a smaller-size particle than a sheet of paper?

Y. DAVID

A. No.

Q. Did you ever observe anything to move through the filter that you detected in some way?

A. No, I did not.

Q. Your report does use the word "suctioned."

What's the definition of that term?

A. To suck is bringing from -- bringing an object from point A to point B by application of a vacuum. So in my report, what I use it for is to indicate that paper clips moved from one point to the other, actually raised from the table base towards the filter containing -- container by the vacuum that the fan is generating behind the filter.

Q. When you said "clips," do you mean these pieces of paper or do you mean like a metal paperclip?

A. You're right, I should have said cutouts.

Q. It's what's depicted on page 14?

A. Yes.

Y. DAVID

Whenever you can let me have a break, that would be great.

Q. That would be fine.

THE VIDEOGRAPHER: We are going off the record at 12:05.

(Recess, 12:05 p.m. to 12:18 p.m.)

THE VIDEOGRAPHER: We are back on the record at 12:18.

BY MS. EATON:

Q. Do you -- sorry. Do you have any indication of how much suction would be required to remove a 10-micron particle from the floor?

A. No, I do not.

Q. And do you have any idea if the Bair Hugger device sitting on the floor could remove a 10-micron particle?

A. Sure.

Q. What's your idea?

A. The idea that the heavier product, like paper cutout, would lift it easily.

Q. That term "easily," is that a scientific term? Does it have a --

MR. BANKSTON: Object to the form.

Y. DAVID

BY MS. EATON:

Q. -- any criteria or quantification you meant by that term?

A. "Easily" is a term describing that there is no need to apply energy or force. And what I meant to say is that if a large number of fairly good-sized paper cutouts were lifted without much effort, that I would consider it to be easily done.

Q. Okay. What kind of paper was the paper you used?

A. It's a 20-pound white paper.

Q. Okay. Do you have any idea what size microns these cutouts represent, how many microns they would reflect?

A. Well, one can see the -- I'll use the word "easily" again, and easily calculate, because we know the size of a bacteria, for example, of 1- to 3-micron, which is a millionth of a millimeter, and I definitely can see that's much smaller than these 2-inches-wide paper.

Q. That's actually a really good question. Do you still have the pieces of

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paper that were used and depicted on page 14?

A. I believe so.

Q. You do?

A. Yes.

Q. If you could provide those or somehow -- because I'd be interested, for example, in what size they are. Do you have measurements of what size they are?

A. They are about 1-by-2 inches cut.

Q. Is there a reason you chose that particular size?

A. No.

Q. Okay.

A. And let me just make sure that I answer you correctly. I saw the piece of papers when I was working with the device back in December, January, February. I hope that I can find them.

Q. If you are able to find them, I would ask you to keep them, and I'm not sure yet what exactly we would do in terms of an exchange or looking at them, but I would just ask that you look when you return to your lab -- do you still have access to the lab

where you did this work?
A. Correct.
Q. Just look and see if you have them, and if you would, I would ask that you keep them.
A. Okay.
Q. So I take it from the answer you gave me that the pieces of paper you used are much larger than 10 microns.
A. Much larger, correct.
Q. You did not -- did I hear you correctly that you did not attempt to suck anything smaller than the pieces of paper depicted on page 14 into a Bair Hugger device?
A. Correct.
Q. Do you have any basis for believing that a Bair Hugger device could remove a 10-micron particle from the floor beyond the work that is depicted on page 14?
A. I believe that that exercise demonstrated that there is sufficient force to lift objects from the bottom of the feet of the Bair Hugger towards the filter that's about 1 -- less than 1 inches high.

Q. Was your purpose in doing the work set out on page 14 to demonstrate that, that the Bair Hugger device could lift things off of the floor?
A. The objective of my examination was to understand how the Bair Hugger is functioning, to familiarize myself with the components and integral -- internal integration of the different components and how the accessories are tied into it, and the understanding of how air is entering, getting heated, controlled, and moved out of the unit towards the blanket. That was my purpose of the examination.
The other question that's relating to clinical performance or heating quantification inside the box or outside the box or lifting a specific object from the floor were not part of my examination and were never part of any attempt on my part to prove something.
Q. So the work that is depicted on page 14, for example, would not, in your mind, scientifically prove that the Bair Hugger

device could lift any particular 10-micron particle off the floor, correct?
A. Correct. It's the concept of how air is flowing into and out and what is being condition internally at the Bair Hugger 750 with these components that I see; the filter, the fan, the heating element, the electronic control, the sensors of the temperature that are put in the hose and how the blanket is connected.
Q. All of those things are why you -- what you were looking at?
A. Correct.
Q. Okay. Was there any active fault code at the time that you turned on the Bair Hugger device?
A. No.
Q. Other than the presence of the historic fault code, did you have any reason to believe that the Bair Hugger device was not performing, at the time you looked at it, in the same way that it was performing at previous times?
A. To answer your question, I need to

know how it was performing at previous time. I have no knowledge how it was performing previous time. It might have been defective and abnormally behaving for quite some time according to the fault codes that have many hours of registration to them prior to me handling it.
But beside the point is that I don't believe that I have any intention of looking at performance.
Q. Okay, yeah, I've heard that and thank you. I just want to --
MR. BANKSTON: I'm going to object to you interrupting his answer. Let him finish his answer. We've done that in every deposition I've been with you, and I've had witnesses go extremely -- let the man finish his answer.
BY MS. EATON:
Q. Could we just -- I do understand the purpose for which you've explained you looked at the device. I just wanted to ask something very specific on page 10 with respect --

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MR. BANKSTON: I object to the form, that you didn't let him finish his answer.

BY MS. EATON:

Q. There is a reference to the oldest fault event occurring about 1939 hours previous to the examination.

Do you see that?

A. Yes.

Q. And then there's another reference to a second event occurring 447 hours previous to the examination? Yes?

A. Yes.

Q. Okay. Did you get the hours -- does that appear along with the fault code on the device?

A. Correct.

Q. Do you -- is there anything about the way the fault code was displayed or any information you were able to get from the device based on your looking at the operator's manual that would tell you if there had been any repair done in response to that fault code?

Y. DAVID

A. No. I cannot tell if it was repaired or attended to.

Q. You just made a statement, I think, about maybe the device was defective for a long time. Do you have any information specifically you could tell me that the fault codes you saw would mean the device was operating in a way that you would call defectively?

A. Sure. If the fault code that I remember seeing as number 8 and number 3 are suggesting that the heater is not functioning properly and it is a faulty condition, then it is the basic functioning of the device to heat and it's not doing it properly.

Q. And is your basis for saying it's not doing it properly your reading of what the fault code meant or something else?

A. I don't understand what it is, "something else."

Q. Is there something about the fault code that you're saying means the device wasn't heating properly?

A. Right. The fault code states that.

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Q. And that's based on your review of the operator's manual of what that fault code meant?

A. Correct.

Q. If I push the device right now, would I be able to access the archived codes in the same way that you did, or has anything changed about the way they would appear?

A. The only change is due to memory limitation and the archive of fault codes in the device I believe limited to five. And if there were additional fault codes occurring, then it will drop the oldest one and will enter the new one into its memory.

Q. Do you know if any fault codes occurred during your operation of the device?

A. I don't believe they did.

Q. You said, if I understood you correctly, that when you checked the fault codes was not when you first took the device out of the box. Is that correct?

A. That --

Q. Yes? Go ahead.

A. That would be a correct estimate,

Y. DAVID

yeah.

Q. Do you recall if you tested the fault codes -- I'm sorry, that's the wrong word.

Do you recall if you checked the fault codes before or after the temperature measurements that you took?

A. It was before I took measurements.

Q. For what purpose did you check the fault codes?

A. For no other reason, just to understand the condition of the product.

Q. Are the photographs in Exhibit 4 taken in connection with the time that you took temperature measurements?

A. No. I believe that was after.

Q. Did you take any photographs in connection with the time that -- I'm sorry. When you took temperature measurements, was that on the same day that you took the device out of the box first?

A. No.

Q. Is there anything else you did on the day that you took temperature

measurements?
A. I recall that I had to spend a significant amount of time to get all the shipping materials from the different spaces, like in the hose and between the IV pole and so on. There are a lot of...
Q. I am not understanding what you mean. You mean you had to remove shipping materials that had been placed in the device for purposes of its shipment?
A. No, but --
Q. Okay. Then what did you mean?
A. If you look at page 11, you can see -- I don't know what you call those white particles inside the shipping box.
Q. Uh-huh.
A. And those were all over.
Q. Were they made of Styrofoam?
A. Yes. And they were getting into all kind of nooks and cracks in the hose and things like that. I remember that it took me some time to clean all that. So that was the things of getting it out of the box and getting it ready for the next step.

Q. Was the unit itself encased in any kind of a plastic bag, or was it just sitting in these pellets?
A. I believe it was just sitting in the pellets.
Q. Were there any pieces of Styrofoam stuck within the louvers of the air intake grate?
A. Yes.
Q. Had any pieces of Styrofoam moved inside of the device?
A. If you call the hose the device, then yes.
Q. What about between -- I'm sorry, on the inside side, the in-compartment side of the filter, was there any Styrofoam visible on the inner compartment of the filter?
A. I see. Not that I remember.
Q. When you -- there's a reference in here to a blanket. How did you obtain the blanket that you used?
A. I requested the device and the blanket, a system, from counsel.
Q. Did the blanket come in the same

box as the Bair Hugger device?
A. No.
Q. Do you know if the blanket came from the same eBay vendor as the device came from?
A. I do not know.
Q. Why did you request the device and the blanket as a system?
A. If my aim is to understand how the forced-air warming is taking aim at achieving its purpose, I need to have all the components connected together and the blanket has a purpose of distributing heat over a surface and maybe a secondary stage filter, I think.
But nevertheless, the blanket is part of the device and I wanted to understand how this system is integrated together, where it's connected, what are the possibility of air moving through the system, including through the blanket, and how does it reach the surgical site.
Q. Was the blanket that you used a -- designated somehow that you could perceive as a Bair Hugger blanket, a use for -- a specific

blanket for use with the Bair Hugger device?
A. Yes. It has a casing, a flexible plastic container, bag, that it has the Bair Hugger name and a catalog number.
Q. Do you recall what number it was, model -- what catalog or model number it was?
A. I probably still have it. No, I don't remember.
Q. I would be interested in that. Do you mean you have the blanket or the bag or both?
A. I believe I have both.
Q. Okay. I would ask that you keep those and I would -- again, I'm not sure what the logistics of any transfer may be, but I would be interested in that if you still have it.
Do you recall what the blanket -- whether it would be -- do you recall how the blanket matches up with any kind of designation of upper body, lower body, under body? And if you don't, just let me know, but...
A. I don't recall the designation. I

can tell you that it looks rectangular in shape.

Q. Does it look like it would be the full length of an adult body or less than the full length of an adult body?

A. Less than the full length.

Q. Does it have any -- does it have any pieces extending out to the side that you might put over arms, for example?

A. No.

Q. Okay. Would it -- have you seen any -- in any of the materials you reviewed, have you seen illustrations of the different kinds of blankets with designations of what they are?

A. Yes.

Q. Do you have an idea of what kind of blanket it was based on that review?

A. Not from memory.

Q. Do you think it would be for placement on the abdomen or placement on the legs? Any sense of that based on your review of stuff?

A. Looks to me like the size of lower

body covering.

Q. When you -- was there more than one time when you put the system together?

A. No.

Q. What space were you in when you put it together?

A. In the lab.

Q. The same lab that is depicted on page 14?

A. Correct.

Q. Where is that lab located? What kind of -- is it your business' lab or a university's lab?

A. No. It's a biomedical device service lab that is in north part of town and that I rent space when I need it.

Q. When you set up the system and took temperature measurements, what was the blanket sitting on?

A. The blanket was sitting on the service bench.

Q. What's that constructed of?

A. Wood.

Q. Was it at the same height,

basically, as the unit, or higher or lower?

A. I would say about the same height.

Q. Was the temperature in the room about 74 degrees at that time as well?

A. Correct.

Q. What instrument did you use to take the temperature measurements?

A. It was a Fluke thermocouple temperature monitor.

Q. Fluke?

A. F-L-U-K-E.

Q. I am not familiar with how a person uses one of those. Could you please explain for me?

A. Sure. It's a battery-operated device that has connectors to sensors and a display, digital display, with ranges. And the device has been recently calibrated within the last, I believe, 30 days of my use of it, was calibrated to gold standard and have been supplied with temperature probe. Those are very similar to the microphone wires we see here that are being used in this deposition on each one of us.

Those microphone-like wires have a thermocouple at the end. That's the name of the device, thermocouple temperature measurement, and the thermocouple, when it is in environment either touching or in a convection environment, the two metals that perform this joint thermocouple is changing in a different ratio and the monitor is able to measure the resistance to electricity based on the expansion of those pieces of metal.

That is very accurate temperature monitor that's used in many research and experiments, and I happened to have that available to me when I rented the space.

Q. Were the perforations on the blanket face-up or face-down when you did your measurements?

A. The perforations were facing the wooden block, facing down.

Q. Where did you place the Fluke device in order to take the measurements?

A. So this thermocouple sensor, you can imagine taking the tip, which is just this microphone without the foam piece, and I taped

it underneath the blanket.
Q. Was it just one thermocouple? I'm sorry, just one probe? Was it just one probe that you taped?
A. No. I believe I had four.
Q. Is it a standard method to use tape to attach it to a surface?
A. It's a standard matter to attach thermocouple to a particular area that you want to measure. You can attach it with many different things. You can just lay it and hoping that the contact is sustained. You can tape it like I did. You can put glue and have it more permanent.
Q. Does the tape -- I'm just trying to get a sense. Does the tape go over the back of the probe that's going to be measuring temperature or is there a way you can tape like a wire or something -- I know this is not a very artful question, but do you understand what I'm asking?
A. Yes. And I think that I can illustrate to you and answer your question very clearly. If you look at the white tapes

that is used here (indicating) to maintain the power cord on this table and you will take a portion, small portion of that, and I put it around the temperature probe. That's how it was attached.
Q. Is there any reason to believe the presence of the tape would affect the temperature measurement?
A. I don't see why. And once again, I did not aim at doing any temperature performance measurement as part of my examination, just to see what happened to the environment.
Q. Where on the surface of the blanket were the -- so the probes you taped were beneath the blanket on the bench side if I heard you correctly. Is that right?
A. That is right.
Q. How wide was the bench compared to the blanket? Did the blanket hang over the sides?
A. Yes.
Q. Okay. Do you have a sense for how much of the blanket was laying over the sides

versus how much was laying flat on the bench?
A. About 2 inches. The blanket was wider about 2 inches than the wooden block.
Q. On each side?
A. On one side.
Q. Were the temperature probes between the blanket and the block or on the overhang? I'm sorry, that was a bad question.
Were the temperature probes on the part of the -- beneath the part of the blanket that was laying flat on the block?
A. Correct.
Q. Okay. Were they out to the edges or were they in the middle? Where were they in connection with the blanket?
A. I divided the blanket into four quarters and it was in each one of the quarters.
Q. Was it in the middle of each quarter?
A. I believe so.
Q. Okay. Did you take notes of what the temperature measurements were?
A. Except the average that is

mentioned in my report, no.
Q. Did you write down the average that's mentioned in your report?
A. That's what in the report is from, probably a note I took, at 36.
Q. And I'm wondering, do you still have the notes that you took?
A. No.
Q. Do you believe that on the notes that you had you just wrote down that one number, 36, or did you write down several measurements that you then averaged to 36?
A. The temperature ranges between the four quarters was insignificant so it didn't take much of a calculation to see the average.
Q. Did you write down any individual data points in your notes?
A. No. I think, one more time, I wanted to make sure that -- I'm not in a position to give you any reliable temperature quantification of that environment. It was a general concept of where it's heading, is it heating, is it cooling, is it doing anything to the blanket, and that's what I wanted to

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see compared to the 74 degrees that we have on the AC thermometer.

Q. Sir, I asked you if you took any notes, and I'm wondering if in your notes that you took, you described for me, you took down individual data points or you only wrote the average. Are you able to tell me that?

A. I think that I did by telling you that the temperature range was all within decimal numbers, so there is no need to take numbers in average when they are about the same.

Q. I'm not asking what there's a need for. I'm asking what you did. Did you write down individual measurements?

MR. BANKSTON: Object to the form.

A. And as I responded to you, no. I took a review of the numbers and came up with the average. That's a sufficient estimate for my purpose.

BY MS. EATON:

Q. You've just said "decimals." Did every one of the four measurements begin with a 36?

Y. DAVID

A. Yeah.

Q. Were any measurements higher than 36 degrees?

A. Not that I recall.

Q. They were all 36.0 degrees exactly?

A. I believe you misrepresent my answer. I said there's no point. I didn't say they're all 36.0.

Q. I'm just trying to understand your answer and perhaps we're not communicating. Were there -- you've said in your report, if we look on your report on page 15, the last sentence of the first paragraph says, "When I measured several areas of a sample blanket, after 30 minutes of operation, I found an average temperature of 36 degrees."

I'm trying to understand what the individual measurements were that led to that average. Are you able to tell me?

MR. BANKSTON: Object to the preamble.

A. And that's perfect, because the sentence is exactly what I'm trying to communicate all day today, and that is I

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looked at the device physical structure. I did not attempt to measure any clinical performance. I put temperature probes because I wanted to understand how the device is operating, not to determine if it is reaching specific clinical warming objective or not. I cannot give you a reliable temperature observation because that was not my aim, and what I saw was 36.0, 36.7, 36.9, variety of 36-point-something that was easy to say that on the average they are 36.

BY MS. EATON:

Q. Are those numbers that you just said, 36.0, 6, 7, 9, are those specific memories or is that just a -- let me stop there.

Do you believe that those were specific readings you got?

A. No.

Q. Did you get any readings that were below 36 degrees?

A. I don't believe so.

Q. And you got some readings that were higher than 36 degrees but you can't be

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precise about exactly how much higher?

A. Well, I think that I'm fairly precise. It's not the aim is to give you a reliable temperature reading, but what I'm telling you is that it's 36 and decimal changes. It's not 38, it's not 39. It's 36-something.

Q. What about 37 degrees? Were any of the readings that you obtained 37 degrees or higher?

A. I don't recall that.

Q. I'm trying to figure out how numbers above 36 degrees averaged to 36 degrees.

A. Very simply. I did not aim to scientifically monitor temperature feature of this device. I think we went over that multiple times today. I will do it one more time just to make sure that it's clear. It's not my aim to give you a reliable temperature quantification of what happened on this device with this blanket, so for me to report an average of 36 is sufficiently because the determination was that it's 36-point-something

and I did not need scientific accuracy beyond the 36 whole number. I did not look for decimal fraction of a degree.

Q. How many temperature measurements did you take?

A. Excuse me, Counsel, I don't understand the question, how many temperature.

Q. There were four probes taped to the blanket, and how many times did you take a measurement from each probe?

A. Just like what my report is saying. I waited 30 minutes and let it stabilize and took a reading.

Q. Did you take a reading from each probe?

A. Mentally I did.

Q. You reviewed the results for each probe? You saw what the result was for each probe?

A. I'm not sure that your word of "result," but I showed the -- I saw the measurement of each probe, yes.

Q. At one point in time after the machine had stabilized for 30 minutes --

A. Correct.

Q. -- did you look at the results -- did you take any other measurements of temperature?

A. I think I said before, the room temperature.

Q. I'm sorry. From the probes that were taped to the blanket, other than this one observation, did you make any other observation of the temperature?

A. I see. No, I believe that's the totality.

Q. Did you take any photographs of that setup?

A. I don't believe so.

Q. Are you familiar with an ASTM testbed for warming blankets?

A. ASTM what?

Q. Are you familiar with the standard for testing the temperature related to a patient warming device in any respect?

A. I'm familiar with the ASTM organization, with their standards. I was a member of one of their committee, F-29,

involved with anesthesia equipment at one time. I do not have specific recollection of what you're referring to as temperature measurement.

Q. There was a document included in...

(David Exhibit 5 marked.)

BY MS. EATON:

Q. I believe you referenced -- I'm sorry, I didn't keep my copy. Let me just ask a different question.

I believe that this test report was contained within the materials you reviewed. Do you recognize it?

MR. BANKSTON: Object to the form.

BY MS. EATON:

Q. Do you recognize this document?

(Document review by witness.)

A. Yeah, I believe I saw that with a color-coded graph.

BY MS. EATON:

Q. On the last page?

A. Yes.

Q. Do you know, if you look on the first page, what the ASTM F-29.01.10 fixture

is for testing convective warming blankets?

A. As we sit here, by heart, no. I'm familiar with ASTM. I'm familiar with the F-29 committee and the family of standards that they developed. It's very easy to obtain that material and to become educated about it. As we sit here today, no, I do not have that information.

Q. And I just want to be clear. Was the temperature measurement that you did related at all to the method, whatever it is, that would be described in this standard?

A. Well, the ASTM, and specifically the F-29 family of standards, are specifically set of standards that allow for product to comply with performance features. They can be a variety of features.

In this particular case it looks like the testing of a convective warming blanket. Since my purpose was nothing of the kind and has nothing to do with a review or establishing or disputing performance of a product and compare it to standard, my protocol in testing and temperature does not

require to follow the ASTM F-29 fixture for testing.

Q. And I'm not saying it did. I was just trying to ask if there is anything -- and so let me start a clean question.

Was there anything about the test method you used that was designed to match or follow any ASTM guidance for testing convective warming air blankets?

A. Nothing that connected to my activity.

Q. If you had already seen the fault code before you did the temperature testing, why did you go ahead and do the temperature testing?

A. For the very simple reason that I wanted to see if the heating element is working at all, if the fan is functioning, and does the air flow through the whole system and out of the perforation in the blanket.

And the reason I made the measurement is to see if this is room air going through that is not being heated by the heating element or the heating element does

contribute to the temperature change.

Q. What did you conclude based on your test?

A. Since the room temperature was much colder than a body temperature of 36 degrees centigrade, it was obvious that the heating element is contributing to warming the air as it's passing through the Bair Hugger device.

Q. On the date that you did the temperature testing, did you do any other thing with the device?

A. Sorry, I didn't hear you.

Q. On the day that you took the temperature test -- I'm sorry, let me start over.

On the day you took temperature measurements, did you do anything else with the device other than prepare it, which you have described?

A. I think we discussed the sucking force.

Q. That was on the same day?

A. Yes.

Q. With the pieces of paper.

A. Yes.

Q. Okay. Anything else?

A. No.

Q. Okay. Any other types of -- any other time you've ever operated the device except for that day? This device depicted in Exhibits 3 and 4.

A. Let me understand your question. You asked me if I ever operated the device other than on that day with the temperature probe?

Q. Correct.

A. The answer is yes.

Q. On how many other occasions did you operate the device?

A. I have no idea.

Q. Did you ever assemble the whole system, including the blanket, on any day other than that day?

A. Yes.

Q. Do you have any sense for how many occasions that was?

A. No. When I go to the lab, I want to make sure that I prepare, I have everything

that I need, and that the system is connectible and fully integrated. So I probably did it before I went to the lab.

Q. Any other observations you've made while operating the device that were relevant to you?

A. Other observations relating to the inability to clean the inside compartment of the device.

Q. That's based on your personal observation, you're saying?

A. Yes.

Q. Okay. What do you mean by that, "inability to clean"?

A. You need to have an engineer taking the product apart and disassemble it in order to get close to the compartment we see in the pictures, and yet it does not allow you entry into the heating element volume. So even if you have engineers that will take it apart, disassemble as I'm describing here, you might be able to get to the fan and the fan blades, but you won't be able to get to the rest of the air flow path through the heating element.

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Q. Do you know what the temperature is inside the heating element?

A. Inside the heating element? No, I don't.

Q. Is there any other area of the inside of the device that one would not be able to get to by doing what you did?

A. The enclosure, as we see in page 15, separate into two large blue parts, giving you an opportunity to understand that there is a large vacuum spaces, empty spaces, that they are subject to environmental spoilage, and you cannot get to cleaning these spaces unless you mechanically apply tools to take those apart, and it's not recommended nor suggested by anybody to do it.

Q. Why do you believe that the blanket serves as a secondary filter?

A. Sorry?

Q. Why do you believe that the blanket serves as a secondary filter?

MR. BANKSTON: Object to the form.

A. I believe it because I think I read it in some of the material that is in my box.

Y. DAVID

BY MS. EATON:

Q. Did you do any testing or measurement or observation related to that?

A. Observation, other than visualizing that it does allow air to come up, no.

Q. Give me a second.

The day that we've been discussing that's depicted on page 14 and includes the temperature measurements, is that, do you believe, in a month that is reflected in the invoices we have, if you would look at Exhibit 2?

A. So what is the question about Exhibit 2?

Q. You know, actually you can look at Exhibit 2 or not, but do you know when you made the measurements?

A. No, I don't remember.

Q. Do you believe it would have been in January 2017 when your description says "device testing"?

A. December 2016 is also examination, examine product.

Q. Right.

Y. DAVID

A. Oh, I see what you're saying, "device testing." January 2017. Makes sense.

Q. Is there any other testing you did on the device except what we've just been discussing?

A. No.

Q. Do you believe that the testing of -- with the paper cutouts and the temperature measurements would have been done in January 2017?

A. The best of my knowledge, I would say yes.

Q. Was anyone else present when any of that work was done?

A. No.

Q. Did you ever make any videos at any time related to your work in this case, anything that you did?

A. No.

THE WITNESS: Are we getting close to lunch?

MS. EATON: Yes. Sure. Why don't we go ahead and take lunch.

THE VIDEOGRAPHER: We are going off the record at 13:13.

(Recess, 1:13 p.m. to 2:14 p.m.)

THE VIDEOGRAPHER: We are back on the record at 14:14.

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(David Exhibit 6 marked.)

BY MS. EATON:

Q. Hello. I have marked as Exhibit 6 a table of contents in one of the binders that you brought today. It's titled "Other Reference Materials." Is that correct?

A. That's correct.

Q. Did you -- how did you receive those materials in Exhibit 6, reflected in Exhibit 6? I'm sorry.

A. Those materials were put in the binder based on how I structure my report.

Q. I'm sorry. Did you receive these materials from someone or did you locate them yourself?

A. It's a combination of me locating and asking counsel to receive -- to obtain those for me.

Q. Are there any documents listed on the table of contents marked as Exhibit 6 that

you yourself obtained?
A. Sure. The ASHRAE standard I obtained myself. The Bair Hugger specification was provided to me. The CDC was provided to me. And the FDA, I put in.
Q. You put in?
A. Yep.
Q. The table of contents refers to ASHRAE Standard 62.1, but what appears to be behind the tab is a series of PowerPoints and an M.D. Anderson Cancer Center document.
Do you know why that is?
A. Yeah. The M.D. Anderson document is an institutional policy relating to how standards should apply to the construction of personal protective environment in similar spaces and using the standard that ASHRAE has structured. So it is under A.
And under B is the Canfield merit rating and filter designation based on the ASHRAE standard as well, so it's under the ASHRAE standard as support material.
Q. And are you thinking that both of those items you've just talked about relate to

ASHRAE Standard 62?
A. To ASHRAE Standard 62, yes.
Q. You were looking at the front page of a PowerPoint there when you said that?
A. Correct.
Q. And how did you obtain that PowerPoint?
A. This is online. Search online.
Q. Okay. You were -- did you look at the actual ASHRAE Standard 62?
MR. BANKSTON: Object to the form.
A. No, I don't believe so.
BY MS. EATON:
Q. Do you know what ASHRAE Standard 62 is?
A. It's indoor ventilation.
Q. Does it apply to hospitals?
A. It's included, healthcare facilities.
Q. Do you have familiarity with the standards in general that apply to hospital settings or hospital operating room settings?
A. In general, I do, yes.
Q. Have you worked with ASHRAE

Standard 62 before?
A. "Worked with" is a large area of involvement. I have used those kind of standards in my line of work.
Q. Have you used that specific standard in your line of work?
A. Yes.
Q. ASHRAE Standard 62?
A. Yes.
Q. Okay. I may come back to that if there's time.
(David Exhibit 7 marked.)
BY MS. EATON:
Q. Deposition Exhibit 7, I've marked the entire notebook, including the table of contents. Is this the material that you refer to in your materials reviewed list concerning other products?
A. That would be correct.
Q. Was it your understanding that that material was provided to me before today?
A. Material provided to you? I don't understand the question.
Q. Do you have any belief that that

material was provided to me, to counsel for 3M, before today?
MR. BANKSTON: Object to the form.
A. I don't know.
BY MS. EATON:
Q. Is that information that you reviewed in coming to your opinions?
A. Yes.
Q. Okay. And is that the information that you pulled off the internet that you were talking about this morning?
A. Not necessarily internet.
Q. From where did you obtain that information if not the internet?
A. Well, I asked counsel about the 510(k)s, I didn't find those. It's a combination between me finding it and asking counsel to provide me.
Q. Okay. So if you would open that notebook again and look at the table of contents, there are several 510(k) summaries. Is that correct? As opposed to full 510(k)s?
A. Yes, I see a couple of summaries.
Q. You're saying the summaries of

510(k)s you were not able to get off of the internet?

A. No, I said the full 510(k)s.

Q. Well, I don't see any full 510(k)s in that document. Have I missed that? I'm sorry. I said "document." I mean notebook.

Is it your belief that you reviewed any full 510(k)s for any other non-3M, non-Bair Hugger products?

A. I think I don't remember exactly, but this might be one that I did not find, the VitaHEAT.

Q. Okay. So you believe that one may have been provided by counsel?

A. Probably. Probably.

Q. And the other materials that are in that book, did you find all of them?

A. I think so, yeah. I don't necessarily recall one way or the other, but I know that I know how to get them.

Q. With respect to the materials that you reviewed about other products in connection with coming to your opinions in this case, is there anything outside of what's

contained in Exhibit 7 and what we discussed this morning with respect to the HotDog?

A. That would be it.

Q. Okay. Did you actually examine any of the devices that are reflected in Exhibit 7 or the HotDog in connection with your work in this case?

A. No.

Q. Have you ever, in your professional -- have you ever -- I'm sorry, let me start over with a clean question.

Have you ever reviewed any of the devices that are listed on the table of contents for Exhibit 7, ever seen them, examined them?

A. That's why I'm looking at the CSZ because I think that I saw that before.

Q. You might have seen that --

A. Yeah.

Q. -- in a hospital?

A. Yeah.

Q. Did you ever examine it for purposes of seeing how it was operated or --

A. Yeah. This was not in a hospital.

It was in outpatient.

Q. Okay. And what -- did you do anything other than just see it?

A. Right. I was in that environment for a different reason.

Q. Is it fair to say that all you did was simply see it in an outpatient environment?

A. Correct.

Q. Did you make any kind of examination or test of that device?

A. No.

Q. Have you ever evaluated any of the devices listed on the table of contents for Exhibit 7 in the course of your professional work?

A. Besides through the literature that is here, no.

Q. In the course of your work outside of this lawsuit, have you ever evaluated any of those devices for a hospital application?

A. I see. No.

Q. I do not believe that we ever received those materials before today, and I

have not had time to really look through them.

MR. BANKSTON: That would be surprising to me because I was specifically asked to get them and pass that along. So I don't know if in that chain it didn't make it, but it would be surprising to me because you have the pictures and they were with the pictures so that's somewhat surprising to me. But if it's not, it's not. I don't know what to tell you.

MS. EATON: I did receive the pictures by e-mail on special request on Friday at the end of the day. I don't believe that those marketing materials were included in what I received.

MR. BANKSTON: You may have not been forwarded everything from Ms. Lewis or whoever it was sent to, because those -- all I can tell you is that I personally made special efforts to collect those and make sure that they were sent in response to that request.

MS. EATON: On Friday?

MR. BANKSTON: On Friday, correct.
MS. EATON: Of last week.
MR. BANKSTON: Correct. And those pictures, I'm also responsible for passing those along. Which is why I'm saying it's somewhat surprising, and I don't know why, if whoever our lead counsel is, in passing those e-mails along, if one didn't get sent or if one hit a spam box for one reason or another, but I can tell you that I am the one who collected those photos and made special efforts to get these materials here to you in response to the request for the marketing materials on the alternative design materials that are cited within his report.
So if you don't have those, I'm not totally prepared now to explain to you why you don't have them.
MS. EATON: That's fine. I just wanted to make a marker that I did not receive them. I don't believe I've received them, unless I made an error in

my e-mails. I don't believe I've received them before today, and I have not had a chance to look through them all.

BY MS. EATON:

Q. So you can close that.

(David Exhibit 8 marked.)

BY MS. EATON:

Q. I've marked as Exhibit 8 a table of contents for literature. Is that literature that you reviewed in connection with your work in this case?

A. Yes.

(David Exhibit 9 marked.)

BY MS. EATON:

Q. I've marked as Exhibit 9 a table of contents for certain documents that I could characterize broadly as company documents. Is it your belief that those would correspond to the listing of materials reviewed in your report?

A. They will correspond to footnotes, yes.

Q. Okay. There's an index that I have

marked as Exhibit 9 that has certain descriptions of the documents. Did you make those descriptions or did someone else make those descriptions?

A. I believe that I have a clerical assistant for doing that.

Q. But who provided the substance of the descriptions?

A. I was given the information and the order where it should be.

Q. Did you dictate the substance of those descriptions on Exhibit 9? Is that what you're saying?

A. I'm saying what I said in -- on the telephone, with a clerk, yes.

Q. Are those all of the 3M or Arizant or Augustine Biomedical documents that you reviewed in connection with your work with this case? I should say I have also a 510(k) binder here, so in addition to that.

A. Okay. Yes.

Q. Were those documents provided to you in a single packet?

A. In a single packet? Provided in

boxes, I guess.

Q. Were the documents listed on Exhibit 9 provided to you all at once, together?

A. I see. No, I don't think so. There are different boxes.

Q. Do you recall over what period of time those documents were provided?

A. I would say probably over a four-month period.

Q. In what years?

A. In the -- late 2016 to early 2017.

Q. Do you know how those documents were selected?

A. Well, they're mostly a response to material that I requested.

Q. What did you request that those would be responsive to?

A. I requested the information about the statement by company officers by plaintiff, management relating to product, product development, to changes to the product, to testing and any field reports that were received.

Q. What kind of field reports are you interested in?
A. In the sales rep conveying information of what they see happening in the field.
Q. Is it your understanding that the binder sitting in front of you contains all documents that would respond to that series of categories you just listed that have been produced in this litigation?
A. I'm not sure that I'm following the question.
Q. Do you believe that you received all documents that have been produced in this litigation that relate to the categories that you just described?
A. I see. I do not know if it's all.
Q. Would you be surprised if all of the design and testing documents for these products are contained in that binder?
A. Are or are not?
Q. Are. Would you be surprised if exhibit -- would it be surprising to you if Exhibit 9 contains all of the testing and

design documents for the Bair Hugger devices?
A. No.
Q. You would expect that to be it?
A. I have no expectation. I wanted the material and reviewed what they provided.
Q. Have you ever been involved in designing a medical device?
A. No.
Q. Have you ever reviewed a design history file?
A. No.
Q. Do you know what a design history file is?
A. Yes.
Q. What is a design history file?
A. It's information collected from the engineering aspect of making a product from beginning to end.
Q. Are there any federal regulations that govern the design of a medical device?
A. Federal regulation design, that regulate the design? No. Federal regulation is looking at general processes, guidelines. There's no requirement, just expectation or

guidelines how to do things.
Q. Do any of the federal regulations that you're aware of relate to how to design a medical device?
A. No.
Q. Are you aware of any industry standard that relates to how to design a medical device?
A. There are many guidelines out there by different groups and professional association, consulting, that create a recommended process, guidelines guiding implementation of ideation or innovation, but those are recommendations and guidelines. There's no mandatory.
Q. Are you familiar with any particular recommendation or guideline for designing a medical device that is a prominent one or often used by medical device manufacturers?
A. Again, for designing, no, I'm not aware. I'm aware of testing, but -- the outcome, but not of design.
Q. And when you're speaking of

testing, are you thinking of, for example, ASTM standards?
A. For example, or AAMI or ANSI.
Q. Would those be related to specific tests and how you conduct specific tests?
A. Correct.
Q. Are you familiar with any industry standard for risk assessment of a medical device?
A. Not as a standard. Again, as a guideline and as a recommendation and acceptable practice, but not mandatory.
Q. And is there any particular guideline or recommendation that you're thinking of when you say that?
A. There are several I pointed out in my report to an organization called MITRE, M-I-T-R-E, and there are others that are provided by the Food and Drug Administration and furthermore by the ANSI organization, A-N-S-I.
Q. The MITRE reference that you provided in your report, is that something that you have worked with before in your

professional capacity outside of litigation?
A. I used it, yes.
Q. It looked to me like that was related to the design of a system. Is that correct?
A. That's correct.
Q. I did not see any discussion in that reference about medical devices, and I just wanted to make sure I didn't miss anything. Is that fair?
A. No, that's correct. The concept there is describing how to identify hazard and do a risk assessment of a system. They are a big conglomerate and then they look at system, and my interest in that was from hospital point of view, looking at disaster preparedness for medical technology.
Q. Have you ever used that MITRE system in advising a hospital about disaster preparedness for medical technology?
A. Correct.
Q. What kind of disaster preparedness are you thinking of? What kind of failures might there be that that would relate to?

A. The disaster planning for healthcare provider is a very important functionality because during any kind of disaster, man-made or natural, the population expected at hospitals will be up and running and able to care for the injured, and nevertheless, hospitals are dependent on systems and subjected to failure themselves.
So this disaster preparedness system is completely targeted; the hospital and electrical grid, telecommunication, a monitoring system of patient, an oxygen line, ventilators. So not one of a kind, but system of equipment functioning. Air conditioning will be one of the systems.
Q. And to the extent that medical devices -- let me ask that differently. Would medical devices even be contemplated within that assessment?
A. Sure.
Q. And to the extent that they would be contemplated, would it relate to how they could continue to function if, for example, the electrical grid goes down?

A. That will be one example.
Q. Is there another example that would relate to how medical devices would function in a disaster?
A. Sure. If you do not have access to supply that the product is using, if an environment as far as air temperature, for example, cannot support the limit of the range of temperature that's designed for this device operation, if it goes outside the limitation, and if you have a situation where gas powering the device has been contaminated.
Q. Have you ever applied ISO standard -- have you ever heard of the International Standards Organization and have any familiarity with its standards?
A. Sure.
Q. Have you ever used or applied ISO Standard 14971?
A. I worked with it. I am not sure that I can tell you that I applied it in a project.
Q. How did you work with it?
A. Well, as part of my experience and

training, I went to seminars. I educated myself as to what the standard's purpose and what the principle of the categories that it addresses, and how one will use it as contrast with other risk assessment programs.
Q. What is ISO 14971? What is it intended -- what is it? What does it apply to?
A. It's basically quality system organization.
Q. I'm sorry. ISO Standard specifically 14971, do you know what that addresses?
A. It's addressed risk management.
Q. For what?
A. For medical devices.
Q. Did you consult that in connection with your work in this case?
A. No, I don't believe so.
Q. You are aware of it?
A. I am.
Q. You're aware that the risk in that standard is evaluated in connection with benefit?

Y. DAVID

A. Risk usually has been evaluated and when you look at the system, the risk -- the benefit-to-risk ratio is a parameter that they take into consideration. But just to have risk assessment, you don't need to bring the benefits in.

Q. In your work in hospitals, do you -- did your role ever involve considering both benefit and risk of certain medical technologies?

A. Sometimes, yes.

Q. If you were making a decision, for example, whether to purchase a particular device, would it be relevant to consider both the benefit and the risk of the device?

A. Somewhere along the consideration that that parameter has an input.

Q. When you were working at a hospital considering that type of framework, did you have any written standards or protocols that you were referencing?

A. I don't think so.

Q. Did you ever create any risk-benefit standard that would provide the

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criteria by which you would evaluate medical technology?

A. I did not create standard. I created processes and protocol. So I did do those.

Q. And in connection with -- were those ever reduced to writing?

A. Those were reduced to writing, correct.

Q. Was there anything in those protocols that would say this is how you should evaluate a benefit?

A. I don't think so.

Q. Within the context of federal regulation of medical devices, is risk evaluated in connection or in context with benefit?

A. Sometimes.

Q. Would you agree that the purpose of federal regulation of medical devices is to provide reasonable assurance of safety and effectiveness of those devices?

A. I agree that that's the FDA mission.

Y. DAVID

Q. Would you agree that under ISO 14971, safety is defined as the absence of an unacceptable risk?

A. As we sit here, I don't recall by heart the words, but that's close to what I would expect to find there.

Q. And would you expect also that in the context of federal regulation, what we are -- what the government is seeking to avoid is an unreasonable risk in the context of how the product is used?

A. That makes sense.

Q. Are you familiar that that is in fact the standard, or no?

A. Because there are classifications of risk, I would modify my response by saying that the risk -- the magnitude of risk.

Q. Are you saying that that's in the regulation?

A. Yes.

Q. The magnitude of risk?

A. Yes.

Q. What regulation are you thinking of?

Y. DAVID

A. The classification.

Q. Class 1, 2 or 3?

A. Correct.

Q. Okay. And that when FDA is considering the risk, it is considering whether the magnitude of risk is unreasonable in light of the overall risk-benefit context.

Would you agree with that?

A. I would agree.

(David Exhibit 10 marked.)

BY MS. EATON:

Q. Exhibit 10 is a table of contents to a 510(k) for the model 505 and the model 750. Is that correct?

A. Yes.

Q. Did you review those documents?

A. Yes.

(David Exhibit 11 marked.)

BY MS. EATON:

Q. And Exhibit 11 is a table of contents for depositions of certain individuals. Is that correct?

(Document review by witness.)

--oOo--

Y. DAVID

BY MS. EATON:

Q. First, just is it correct that Exhibit 11 is a table of contents listing certain depositions?

A. Yes.

Q. And then were you wanting -- I'm estimating that perhaps you were wanting to compare that list to the list contained in your report?

A. Correct.

Q. Okay. So Exhibit 3 --

A. I need my glasses.

Q. It lists nine depositions on Exhibit 3. Are there nine there?

A. There are nine, yes.

Q. Okay. I don't see a deposition of Mr. Ulatowski in Exhibit 11 and I didn't see it in the box. Do you believe you have in some form reviewed the deposition of Mr. Ulatowski?

A. I believe it's inserted here.

Q. I don't need you to look for it right now, that's okay. You do believe you've reviewed that deposition, correct?

Y. DAVID

A. Yes.

Q. And do you believe you have reviewed any other deposition besides Mr. Ulatowski's that we would not find in Exhibit 11 or in Exhibit 3?

A. No. But I believe that I inserted it.

Q. Into one of the tabs?

A. Yes.

Q. Okay. I didn't see any table of contents for any expert reports. Do you believe that you brought with you today the expert reports that you reviewed?

Just to show you, your box is now empty. And also, to be complete, there is a document I pulled from the box. Just it wasn't in a notebook. It's titled "Medical Devices and the Public's Health: The FDA 510(k) Clearance Process At 35 Years."

A. There's only one page of Ulatowski deposition here. I thought that I put it in. I don't know what happened.

Q. So now looking in your notebook, you're seeing one page of the Ulatowski

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deposition but you believe you had the whole transcript?

A. Right.

Q. Okay. Any other transcript you believe you had?

A. No.

Q. Any other expert report you believe you had that's -- other than the three listed in Exhibit 3?

A. No.

Q. How did you obtain this document, "Medical Devices and the Public's Health," about the 510(k) clearance process?

A. I've asked counsel to produce a hard copy.

Q. How did you know of this document?

A. Part of my practice is to stay on top of what's happening with the regulatory field and it's one of the things that I would be reading.

Q. Okay. I think you said something about an FDA -- this document -- okay, let me -- I'm sorry, let me take that and ask differently.

Y. DAVID

Was there any document that was an FDA guidance that you used to inform your opinions about the regulatory history of the Bair Hugger devices?

A. Can you ask me again the question?

Q. Was there any specific FDA guidance document that informed your evaluation of the regulatory history of the Bair Hugger devices?

MR. BANKSTON: Object to the form.

A. I think the overall environment of FDA regulation documents like the 510(k) submission process.

BY MS. EATON:

Q. Have you ever worked within the Office of Device Evaluation for FDA?

A. Worked for the FDA? No. I just serve as a consultant for them.

Q. I do want to get to that in a moment, so let me just ask some specific questions. You've never been an employee of the FDA. Is that correct?

A. That is correct.

Q. You have never worked within the Office of Device Evaluation?

Y. DAVID

A. That is correct.
Q. Have you ever worked within the Office of Compliance?
A. I did not.
Q. Have you ever taken part in reviewing a 510(k) application for clearance?
A. Yes.
Q. On behalf of the FDA?
A. Yes.
Q. In what context?
A. As a member of the advisory panel.
Q. Okay. When did you do that work?
A. It's a public record when the panel is called to admitting. You can find them online. I don't recall when it was done.
Q. Was it once or more than once?
A. More than once.
Q. How many devices -- you're saying as part of your work on the panel, you've reviewed a 510(k) application?
A. Yes.
Q. Okay. For how many devices?
A. I don't know, four, five.
Q. Do you recall what the devices are?

Y. DAVID

A. No.
Q. And I want to be clear. Let's take a look at your CV, which is within Exhibit 3. If you would please turn to your CV and find for me which specific panel you're referring to.
A. On page 3 it's the General Hospital and Personal Use Devices Panel.
Q. Okay. The time frame here listed is 1993 to present for that. Is that correct, that you are still on that panel?
A. Yes.
Q. And have you been on that panel since 1993 continuously?
A. Since 1993, correct.
Q. Is that type of work something that is -- is there any kind of regular meeting of that panel?
A. No.
Q. How many times was the panel called that you participated in?
A. I don't recall. But like I said, it's a public record.
Q. Do you remember the specific

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questions the panel was being asked at the times that you met?
A. The specific question? No, I don't remember.
Q. Do you remember the scope of the review you were asked to make?
A. The scope of the review was to determine if the instructions for use are sufficiently covering the risk associated with the use.
Q. In all of the cases that you recall, that was your scope?
A. In all the cases?
Q. I'm sorry. I believe I heard you say you thought -- I should -- I should say that differently.
You said you recalled that you reviewed perhaps four or five devices. Did that occur in one panel meeting or over several panel meetings?
A. Over several.
Q. In each situation where you were asked to review something for this panel that you've identified, was the scope of the review

Y. DAVID

to determine if IFUs sufficiently covered the risks?
A. No. There were additional charges for the panel. A second one was to determine if the submitter identified sufficient risk that might be existing in the clinical environment when the device is in use.
Q. Any other scope of review you could recall?
A. Is there sufficient -- if there is sufficient content in the classification of the device to ensure safety when this device is deployed, or there is a need for special control to be added.
Q. Do you recall what device that was?
A. That was some kind of injector.
Q. Injector?
A. Yes.
Q. Do you recall what kind of devices you reviewed IFUs for?
A. No.
Q. Any other scope of review you can recall?
A. There is another panel on the same

page 3 that I identify as a consultant for FDA on neurological devices.

Q. Yes.

A. And in that meeting, there was a question about 510(k) that was submitted for a drug that is using a device to deliver it.

Q. Do you recall the specific combination device?

A. Not beyond that.

Q. I'm sorry?

A. Not beyond that.

Q. Okay. With respect to your work on the neurological devices panel or for neurological devices, this entry in your CV, was that one product review the extent of your work for this category?

A. I believe so.

Q. When is the last time that you were called to consult as part of the panel in the Center for Devices and Radiologic Health?

A. Oh, that was quite some time ago. Maybe 2006.

Q. I'm not sure how far back the FDA records go online and how easy it would be for

me to find any of the records that you're referring to. Is it your belief that you participated every time the General Hospital and Personal Use Devices Panel has been called since 1993?

A. No. There are times that I was involved with projects overseas and hospitals in China, Israel, Italy, and I wasn't available for a meeting. There are times that due to work at the Medical Center I could not attend, so, no, I did not attend all the meetings.

Q. Do you have any materials from which you would look and let me know which times you did participate and in what years and for what products?

A. No. This material got lost in a flood that the Medical Center suffered, so I don't have that.

Q. Is there a particular expertise you have that you're aware results in you being chosen or asked to serve on certain panels?

A. Sure.

Q. What is that expertise?

A. Biomedical engineering, trained and practice in the largest medical center in the country so I am bringing the engineering and the clinical exposure and appreciation for processes involve technology in patient care environment. It's a unique combination.

Q. Have you ever been involved in reviewing a question of whether a device was substantially equivalent to a predicate device?

A. During the panel convening that the question would come up, yes.

Q. You have a specific recollection that you've been asked to review that question?

A. I have specific recollection that that was one of the subjects that we're asked to consult upon. I don't have a specific recollection what device was involved.

Q. Do you have a specific recollection of what types of information were consulted or considered in that, in connection with that question?

A. From my angle, what I remember are

questions relating to biomedical engineering in the clinical environment. So if I'm not mistaken, one of the devices was a cleaning and sterilizing equipment for proctoscopes, scopes that are used in the rectum, and how you clean it between uses. And this cleaner has a predicate device that said here is why we are substantially equivalent.

The question was relating to how in the real world, in a clinical environment, this other device is being used.

Q. Any other instance you can recall being asked to evaluate a substantial equivalence question?

A. No.

Q. Have you ever inspected a manufacturer on behalf of FDA?

A. No.

Q. Have you ever had any input into any FDA compliance decision?

A. No.

Q. Have you ever been consulted in any of these panels with respect to whether a device was adulterated or misbranded?

Y. DAVID

A. No.

Q. What is the definition of an adulterated device?

A. A device that has been put on the market with -- featuring performances other than were reported.

Q. Reported to whom?

A. To the regulatory agency.

Q. How does something become a specification or standard against which the regulatory agency would have the ability to compare to determine if a device is adulterated?

A. By comparing the information submitted in the -- if you will take it as a class 2 device, in the 510(k) documents with the actual device performing in the field.

Q. The device would need to be manufactured to the specification stated to the FDA. Is that correct?

A. Would have to, yes.

Q. What is the definition of misbranding?

A. Misbranding is providing

Y. DAVID

information that is lacking sufficient assurance of safe application.

Q. From where do you get that definition?

A. Where I get the information, I will go to the Code of Federal Regulation.

Q. And do you know where in the Code of Federal Regulation I will find that definition?

A. I think my report is identifying a specific area. There is too much material here for me to remember by heart.

Q. Have you ever been involved on behalf of a company responding to any statement by FDA that a device was adulterated or misbranded in FDA's view?

A. I have not been involved in a company such as that.

Q. Have you ever in your professional capacity in any way, outside of litigation, applied, interpreted or addressed the words "adulterated" or "misbranded"?

A. Sure.

Q. Tell me about that.

Y. DAVID

A. Throughout my practice at the Medical Center, I was evaluating medical technologies as we discussed this morning and I would look to see that information provided to me by the manufacturers is the same that the device is presenting and that the claims that are being made for the device performance are the same that I'm measuring.

Q. Okay. In terms of the terms "adulterated" and "misbranded," I meant the application of the statute. Would you be applying a federal statute or regulation in the course of your work?

A. No. I'm not involved in the legal profession.

Q. And do you have any understanding about whether -- let's see. Do you have any understanding that FDA ever communicates to companies a statement that a device is either adulterated or misbranded?

A. The FDA would.

Q. In what context would the FDA do that?

A. If they identify that to be the

Y. DAVID

case. It can be product investigation, a facility inspection, field complaints.

Q. Have you ever heard of a document called a warning letter?

A. Yes.

Q. Have you ever reviewed a warning letter in your professional capacity outside of litigation?

A. You're asking me questions that I need to scan 40 years of practice, and my response to you would be simply yes because I've worked with thousands and thousands of manufacturers. And as I told you this morning, I was responsible for over 25,000 medical devices and every now and then there will be a warning letter issued. There will be other ways to recall or field modification, and I'm familiar with the process, familiar with the communication and have worked with them.

Q. Okay. In the course of your work in the hospital, are you saying as the director of the biomedical engineering department you might encounter a warning

letter for a product? Is that what you mean to say? Or have I interpreted you correctly?

A. Yes.

Q. Would you go looking for that type of communication from FDA or would you sometimes receive it?

A. No. I would look for it.

Q. Okay. Why would you look for it?

A. Because I might receive information from a clinician that they cannot access a device or accessory anymore and I would look to see if that's one of the reasons.

Q. Did you make any search in this case to see if there were any warning letters issued by FDA to 3M or Arizant or Augustine?

A. The work I've done are in these binders, so if you don't see it here, I did not do it.

Q. When you were working for a hospital, how would you go look for a warning letter? What method would you use?

A. Oh, there's a couple of ways. One is communicate with the manufacturer directly and raise the issue and ask the question.

Secondary is to visit with the FDA publicly accessible database.

Q. And did you visit with the FDA publicly accessible database in this case at all?

A. On the issue of warning letters, no.

Q. Would it be important to you to know if the FDA has issued a warning letter or not to 3M with respect to the Bair Hugger device?

A. I think it will be important if I would have a base to think that there is a base for suggesting someone exist. But like I said before, since there was no recall of the product from the field, since there was no field corrections or "Dear Doctor" letters issued by the manufacturers, I did not imagine that one exists.

Q. What is the basis for your statement that there were no "Dear Doctor" letters or recalls for the product?

A. Because as I'm reviewing the various databases and information provided to

me and literature that I read, I did not see that.

Q. Did you review any databases to see if there had been a recall or a field notice?

A. I think we discussed that I did not look for warning letters.

Q. But I'm asking a different question. Did you look for recall notices?

A. Did I look for recall notices? No, I don't think so.

Q. Do you know if FDA has inspected 3M with respect to the Bair Hugger device since 2010? Since it acquired the product, I should say.

A. I'm aware of one EIR. I don't remember the year that it was done.

Q. I believe you do reference an EIR in your report. Is that the one you're thinking of?

A. Yes.

Q. Do you know if since the date of that EIR there has been any other inspection by FDA of 3M with respect to the Bair Hugger device?

A. No.

Q. Would that matter to you?

A. If there was another inspection relating to the Bair Hugger at the manufacturing site, that would be important.

Q. Would it matter to you if FDA had considered specifically whether or not -- let me ask you a different question.

Why?

A. Why? Because usually you can see what is the reason that the inspection took place or initiated it for cause or a routine periodic site inspection. Secondary, you can see what was the target of the visits, what are the issues that were raised during the visit or the observation, as I call it. And finally, what was the resolution.

Q. And if FDA specifically considered the question of whether Bair Hugger devices increased infection risk, for example, and concluded that they made no observations or findings at the end of that inspection, would that be important to you?

A. It will be important to read, yes.

Y. DAVID

Q. In your professional capacity outside of litigation, have you ever had reason to review an inspection report from the agency?

A. Outside litigation, no.

Q. And have you ever consulted with FDA in the preparation of an Establishment Inspection Report?

A. No.

Q. You said that you have consulted with -- I'm sorry, let me just ask a better question.

Have you ever consulted with medical device companies about regulatory topics?

A. Yes.

Q. Are you able to identify any of the companies for me?

A. On page 2 of my CV under "Professional Experience," you have "Interim CEO, Canopy Edge." That's specifically involved with preparing the product for regulatory submission.

Q. What is that product?

Y. DAVID

A. It is a vascular catheter.

Q. Has a 510(k) -- I'm sorry. Will that be submitted as a 510(k) or a PMA, do you know?

A. It is still being reviewed.

Q. Any other medical device for which you've provided consulting on regulatory topics?

A. There are two other companies. One is called, I believe, Carmel Industries, C-A-R-M-E-L. And the other one is Begamed, B-E-G-A-M-E-D.

Q. What products?

A. Begamed.

Q. Were there specific products?

A. Begamed's product is laparoscopic suture, surgical instrument. And Carmel Industry is a software-based labor and delivery package.

Q. With respect to these three products that you've just identified, what is your role? What type of regulatory advice are you providing?

A. Wait a second. There is one more.

Y. DAVID

There is one more and I can't remember the name. But their product, this additional entity, their product is a brain stimulator. And let me answer your question about what they asked me to do. The brain stimulator was going to submit a 510(k) and wanted to know what are the electrical safety terms and conditions that their testing needed to demonstrate compliance with.

Q. Okay.

A. IEC 60601-1.

The Carmel Industry, they wanted to know if there is a predicate device to their product that they can use for substantial equivalency.

The Begamed wanted to understand if their product will be qualified for 510(k) if there are substantial equivalent predicate devices and if there is a requirement for animal testing.

Q. Are sutures what class?

A. Class 2.

Q. What about the software-based labor and delivery package?

Y. DAVID

A. I don't remember.

Q. Do you remember for the brain stimulator?

A. Class 2.

Q. And the vascular catheter is still under evaluation?

A. Correct.

Q. For the vascular catheter, what is the advice you're being asked about to provide?

A. What type of testing and information will be required for submission.

Whenever we can take a break...

Q. Pardon? Sure.

THE VIDEOGRAPHER: We are going off the record at 15:20.

(Recess, 3:20 p.m. to 3:32 p.m.)

THE VIDEOGRAPHER: We are back on the record at 15:32.

BY MS. EATON:

Q. Dr. David, have you ever designed a patient warming device?

A. No.

Q. Have you ever made or published any

presentation on Bair Hugger devices?
A. No.
Q. Before your work in this case, had you ever read any studies related to Bair Hugger devices?
A. No.
Q. At any time, have you performed testing related to Bair Hugger devices other than what we have discussed today?
A. No.
Q. At any time, have you performed research related to Bair Hugger devices that is not either reflected in your report or in what we have discussed today?
A. No.
Q. Have you undertaken any effort -- sorry, let me ask that differently.
Before your work in this case, had you reviewed any hospital practices with respect to Bair Hugger devices?
A. A specific brand name Bair Hugger, no. But relating to patient warming, yes.
Q. What had you reviewed related to patient warming prior to your work in this

case?
A. Patient warming is a very important part of maintaining patient condition during disease management and following surgery or during trauma, so as part of my responsibility as director of biomedical engineering, for over 30 years I was involved in reviewing warming devices for adult and pediatric patients using either a literally oven-warmed blanket or devices that use fluids to warm patients or cool them or radiation-based devices that they are used in different environments.
The specific sensitivity that I became very familiar with the warming technology of patients is the one involving pediatrics, and we were having a very interesting project where we were trying to put warming devices in the emergency room, in the trauma center where the ambulances would bring babies, and determine how fast we can bring their body temperature up in those trauma situations.
And we were putting an infrared

warming device in the ceiling of the trauma center and making testing and examination of mannequin, small size, having ice cube on them, and determine the temperature change of the body. And this specific example that I became intimately familiar with the issue of maintaining or warming patients under trauma situations.
The other example that I would like to bring in front of you is the neonatology arena where premature babies are born and are not able to maintain their body temperature, not because of trauma or disease, just because of their stage in early life. And those babies are tremendously sensitive to body core temperatures and it's very difficult to warm them up without causing skin damage.
So infant warmers, Isolettes, those are warm air, forced warm air contraption boxes that you put babies in and need to have specific monitoring for the humidity and the temperature inside to make sure that the babies are not drying up and not being basically cooked.

And we did many studies and published several research papers on that, and I developed a protocol to -- how to test those devices later on in their life. So once we developed it, we learned how to use it and how to maintain and service it.
Q. Did you mean later on in the life of the device or --
A. Correct, yes. Thank you.
Q. That's what I thought in context as opposed to the life of the babies.
Did you do -- you meant the device?
A. Yes.
Q. Okay. Did any aspect of your testing or evaluation with respect to the Isolettes used for premature babies relate to contamination or infection risk?
A. It has that aspect and we have epidemiologists that were part of the study and that was their responsibility to collect the data and look at the statistics. So it was not something that I would do.
Q. Okay. Are you familiar with any of their determinations or the results of their

determinations about what factors might affect contamination or infection risk? Let me say that differently.

Do you know what they were even looking at?

A. Yes, I know what they were looking at and how they were measuring it, but that was not my part or responsibility in that line of work.

Q. What were they measuring?

A. They're basically looking at cultures and swabs and looking at spores and bacteria growth and colony-forming units, CFUs, and changes in those specific area of where the air is going.

Q. Were those taken from inside of the baby-warming box?

A. Correct.

Q. That was not work you were involved with?

A. Correct.

Q. Did you mean to say they were epidemiologists doing that?

A. Yes.

Q. Do you have any expertise in determining how one would test for bacteria in an environment?

A. I would refer to the expert on that. I have working knowledge, as we just described, being in the environment, seeing what they're collecting. But I wouldn't present myself as expert in that field.

Q. Okay. With respect to the first situation you mentioned, pediatric trauma, was that heat -- I'm sorry, let me say that differently.

Were those patients enclosed in any way to help with warming, or were they simply placed in a room?

A. You're right. What one needs to think about that during trauma, there is a large number of clinicians involved with things. There might be an anesthesiologist and a surgeon and a nurse. Everybody has something to do with the patient, so the patient cannot be contained. The patient is definitely open. It is environment similar to operating room in that there is a central

surgical table. Hopefully you don't have to do surgery there, but that's how you get access, 360 degrees around the patient, by the different people, and that's what was the study involved with.

Q. Was that a published study?

A. I think that the trauma surgeon -- the trauma physician, he is not -- she is not a surgeon -- continues it. I'm not sure if it was published or where was it published. But she was definitely making presentation about it at different meetings.

Q. Was there a particular warming technology that you ultimately decided upon in that situation?

A. We tried different things and we settled on the radiation panel that came from the ceiling and were dropped on the patient once the patient was in place.

The drawback was that the heating element, the radiated heating element, is heating, nondiscriminatorily, anybody in the environment, not just the patient. So individuals that were tall and closer to the

radiating panel were absorbing more heat than the patient him or herself. That was a drawback.

Q. Was a consideration of contamination or infection risk any part of the evaluation in that trauma setting?

A. Not in that study, no.

Q. Any other time in your work outside of litigation that you have been personally involved in evaluating patient warming?

A. Yes. The other example would be in the cardiovascular theater, cardiovascular operating room. I don't know, Counsel, if you're aware, but the St. Luke's Episcopal Hospital that I was involved with is the home of the Texas Heart Institute, which is the highest-volume heart surgery hospital -- institution in the country, maybe in the world.

So they are having significant amount of large volume of heart surgery with patients that are being cooled down on purposely to slow the metabolism and blood-brain barrier.

Y. DAVID

Those patients are expected to be well monitored and controlled as far as where their core temperature is, and when they are being brought back, there should be a certain rate of core temperature rising that one should expect to see, no faster, no slower. You do that with what the CDC meeting was here about, fluid warming and cooling devices. And you circulate the blood through a cooler element or a heating element, and these heating or cooling elements are devices that I was responsible for and participated in the study.

We published a couple of studies on those -- I don't think that they are on my CV -- at the Texas Heart Institute Journal about the temperature control devices for postcardiac surgery, and I think there is one study that is in my list that is looking at outcome of patient that underwent cardiac surgery and their scalp temperature did not rise fast enough to predict their outcome.

Q. Did any of the studies that you took part in or the publications have anything

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to do with infection risk?

A. Of course when you're talking about the fluid-based warm or cooling device like in the cardiovascular area, when you put ice in a container and circulate blood around it or when you put heating element and circulate blood around it, of course there is the issue of infection and containment of bioburden pathogens. But once again, I was lucky to be in an institution that have their own expertise in that field, and that was not something that I was doing.

Q. Do you know what kind of heater/cooler device was used in St. Luke's Hospital at any time?

A. Yes, I know. I was going to say COBE, C-O-B-E, maybe Cincinnati Sub-Zero. There's another big manufacturer of heart-lung bypass machines that use those devices. I don't recall the brand.

Q. Do you still consult with the biomedical or work for the biomedical engineering department of any hospital right now?

Y. DAVID

A. I still have on-demand consultation with the hospital in Silicon Valley, and I finished consulting with the Adventist Healthcare System in California, who is a biomedical program. So right now, as of today, just on-demand.

Q. The reference you made, I think, to the heater/cooler devices related to the HICPAC -- H-I-C-P-A-C -- document you cited. Is that right?

A. Right.

Q. Have you been involved with any hospital in assessing its practices in light of the issue that is described there?

A. I don't think so.

Q. Have you been involved in consulting with any hospital with respect to the use of heater/cooler devices and whether or not the use of those poses any infection risk?

A. Well, naturally, for three decades or so I did that here at the Texas Medical Center and I described those occasions. Prior to that, I was at West Virginia University

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Medical Center and, again, the cardiovascular program was at the time developed and I worked with Dr. Tarnay, who was a cardiovascular surgeon, about cooling and warming patients with particular devices at the time.

But I don't believe that my involvement was in the area of infections or infection prevention.

Q. Do you recall any discussion, in any of your work outside of litigation, where a hospital was considering removing devices from the operating room because of air blowing from the devices?

A. Not exactly what you are asking, but I was involved in reviewing and evaluating operating room pollutions from anesthesia-based gases that are expelled from a patient after they breathe it. And the records are suggesting that a minute amount of those gases, if exposed by operating room staff, that person, people, would lead to miscarriages and other undesirable outcome.

So I was involved in study to monitor the influence of air exchanges in the

surgical theater and the amount of gas coming from the end of the anesthesia machine when mannequins were connected with simulated lungs to them. That probably is as close as I can come to your question.

Q. Have you ever been involved in designing a cleaning protocol for an operating room or for the equipment in it?

A. There is equipment that is being circulated through the operating room, not necessarily you would call it operating room fixed equipment, but the specific example I have in mind for you is infusion pump, and drug administration medical devices such as infusion pump are probably in the thousands in quantity in hospitals around the country and they are being used in the emergency room, on the general floor, in the operating room, and they are circulating through various environments.

I was involved with the central processing supply team that looked at means to clean and disinfect those pumps once they come out of the patient arena, areas. And that's

probably kind of answering the question that you have for me.

Q. Before I ask you if you could tell us about that, is that the only example that you can think of where you were involved in developing a cleaning protocol for either an operating room or the equipment in it?

A. At the cardiovascular room in St. Luke's Episcopal Hospital and Texas Heart Institute, the amount of equipment in those cardiovascular rooms in volume is tremendously large and the cleaning that needs to be taking place between patient use is very important. I was part of the panel that reviewed. I don't think that I wrote procedures or protocol how to, but I did participate in determination of what agents and when it should be used and how to use it on medical devices.

Q. Was that type of determination also something you were involved with with respect to the infusion pumps?

A. Correct.

Q. Which agents in either situation

were selected, do you recall?

A. No, I don't recall because they have brand name, germicide -- germicide or -- they have a specific brand name at the time that were picked up, and I don't remember.

Q. And do you remember what the chemicals were, separate from the brand names?

A. Those were agents that were -- that are able to penetrate biofilm and kill bacteria. I don't remember the names.

Q. Were these agents for use on the outside of medical equipment or on the inside of medical equipment?

A. By a majority, they were on the outside. However, some equipment like the warming/cooling circulating device in cardiovascular operating room has tanks that you have accessibility to the inside of their container, so it was used inside as well.

Q. Were you part of determining the cleaning protocol for the heater/cooler units?

A. I was part of the team. I wouldn't say that I determined how it should be done, but I was part of the team and my expertise

came from the biomedical engineering, for example, to make sure that the agent is not damaging the equipment.

Q. With respect to hoses used in operating rooms, that would be an important consideration, right? Not damaging the equipment with the cleaning agent?

A. Right.

Q. Were you involved in determining the interval of cleaning for any of the equipment you've identified?

A. I would bring my recommendation after I consulted with the manufacturers on that, so we will present specific scenario. That's how many patients a day we expect this device to be used on, these are the agents we would like to use, and this is the process we will use them. And I would expect the manufacturer to tell me what will be the impact on the device.

Q. So once the team you were working on -- let me just make sure I understood that. The team you were working with would determine what they would wish to do and then consult

with the manufacturer to see if that would be posing a risk on device integrity? Is that what you said?

A. That would be a fair conclusion, yes.

Q. Okay. I'm sorry, I meant within -- within the team, did you have expertise that was being drawn upon with respect to the interval for cleaning?

A. I don't think so.

Q. Okay. Do you know how the team went about validating -- was it part of the team effort to validate particular agents to see if they would be effective?

A. Yes. There was a trial period of an agent being used and there were specific observation on different part of the cleaning material. Like if you mentioned hoses, there would be a descriptor of how to review possible changes in the physical performance, physical present -- appearance of the hose.

If there is polyvinyl somewhere that is more flexible, if they are metal -- I was very concerned about labeling. I was

concerned that a warning and labeling and how to increase or decrease power on something will not be visible after a while, so all those were put into a testing periodicity with observation being collected.

Q. Do you have any familiarity with the tests that were conducted to determine kill-off of bacteria and whether that was sufficient?

A. In the example I gave you, no.

Q. Were you ever a person who provided expert advice about how to determine if a cleaning agent was killing sufficient bacteria?

A. I would refer to the expert on that.

Q. And that would not be you?

A. It will not be me.

Q. Are you familiar with the concept of a sterile device?

A. Yes.

Q. All devices are not sterile. Is that correct?

A. That is a correct statement.

Q. The operating room contains many devices that are not sterile. Is that correct?

A. That is correct.

Q. Would you agree that air is not sterile?

A. Depends where.

Q. In an operating room?

A. I will agree with that.

Q. Will you agree that people are not sterile?

A. You mean as producing offspring or as --

Q. Ha. No. I mean as producing contamination, bacteria. Or containing.

A. I agree with that, yes.

Q. A surgeon, after scrubbing, for example, is not sterile, correct?

A. The surgeon himself is not. The outside layer, it is.

Q. The outside layer of what?

A. Of what the surgeon has on him.

Q. Do you believe that the surgeon's clothing is sterile?

A. Yes.

Q. Do you believe it remains sterile once it's outside the package?

A. I see what you're saying. It's a good point. I agree with it.

Q. I think the record is confused.

Once the surgeon's clothes are out of their packaging and on the surgeon, are they sterile?

A. They are still sterile until they either touch or impinge a nonsterile object.

Q. And in normal use in an operating room, would you expect the surgeon's clothes to become contaminated to some degree?

MR. BANKSTON: Object to the form.

A. You're taking me to an area that I didn't study, so I cannot respond to the question.

BY MS. EATON:

Q. After prepping, do you believe a patient is sterile?

A. The area that was prepped, yes.

Q. What definition do you have of sterile?

A. I'll have to look it up.
Q. Okay. Do you have in mind, as you sit here today, any particular definition of sterility?
A. Free from pathogen above certain level.
Q. Okay. And do you know what that level is?
A. Just by heart, no.
Q. Okay. Is that a standard that you ever applied, that you were the expert applying?
A. No. It's not something that I applied.
Q. Would you agree that an operating room doesn't have to be sterile in order to proceed with surgery?
A. That is a difficult statement to take because not being sterile have different level of dirtiness to it. So I don't think that a filthy operating room is appropriate.
Q. Did your job ever involve determining what standard of pathogenic organisms could be in an operating room for it

to be acceptable?
A. No, not my area of expertise.
Q. Are there people, to your understanding, in hospitals who do address that?
A. Yes.
Q. Do those people address the levels of contamination that can be present on surfaces in the operating room?
A. I have no knowledge of their standards.
Q. Okay. In your experience, are operating room floors cleaned?
A. "Cleaned" is an open-ended word and I agree with it, yes.
Q. Are practices taken to clean operating room floors in the hospitals that you've worked in?
A. I didn't understand the question.
Q. Do people take steps to clean operating room floors in the hospitals you've worked in?
A. Oh, yeah, sure.
Q. How frequently have the floors been

cleaned, to your observation, in the hospitals you've worked in, in operating rooms?
A. Every day.
Q. How many times a day?
A. Depends on the designation of the operating room.
Q. What about an operating room where orthopedic surgery would take place? How many times a day?
A. They will clean it between uses.
Q. Does that mean between every surgery?
A. Between every orthopedic procedures, yes.
Q. Do you know what cleaning agents are used on the floor?
A. No.
Q. Do you know if the standards for cleaning -- I'm sorry. Do you know if the cleaning agents used on the floor for orthopedic surgeries at the hospitals where you've worked changed at all during the time you worked there?
A. Yes.

Q. Do you know what chemical they were changed from or to?
A. No, but as I was working in those orthopedics operating room, I could see different colors and different smells at times as they were cleaning the floors and I was working on the equipment.
Q. Have you ever seen an orthopedic surgery in process?
A. Oh, yeah.
Q. Are drills and saws used during that surgery?
A. It is like a spare parts garage. Tools, hammers, drills, saws, a variety of implants. As a matter of fact, it might shock some lay people to see how much physical activity is taking place there.
Q. When those saws or drills or other equipment are used -- I'm sorry, let me ask a better question.
Is some of that equipment we just talked about electrical equipment?
A. Yeah. Some is air-driven, pressured air. Some are electrical driven.

Y. DAVID

Q. When those pieces of equipment are used in orthopedic surgery, do they cause the release of particles into the air?

A. They do.

Q. You can see them?

A. At times you can see them.

Q. Do those devices, any of them, blow air?

A. I don't know if I would call it blowing air. They have electrical connections and they might be driven by pressured air that would spin a turbine, but I'm not sure that they are blowing outside.

Q. That's a good distinction. So some of -- which pieces of equipment are you thinking of that are driven by turbines?

A. There are drills that are using air as compared to saws that are using electric power.

Q. Do the saws have a cooling fan for the electrical component?

A. No. The circulating nurse usually will use fluid to cool the area and all that will go down the floor.

Y. DAVID

Q. Have you ever become aware of any test or comparison of the volume or quantity or type of particles emitted from various equipment used in an operating room?

A. No. I don't believe that I was involved in such study.

Q. Are you aware of any FDA regulation requiring there to be a filter on a patient warming device?

A. I'm not aware of an FDA regulation that states that the filter must be part of the design. The FDA does not get into the design details but rather the performance and the operation of the total system. I'm aware of the desire to comply with safe deployment of equipment in the operating room, and if filter is one mechanism to make this device safe, then there should be a filter there.

Q. Separate from the general considerations that you just set forth, are you aware of any specific standard that has been issued or adopted by FDA regulation that would require a filter on a patient warming device?

Y. DAVID

MR. BANKSTON: Object to the form.

A. I don't believe that the FDA's role is to determine how technology is being designed and delivered to clinical site. The FDA is, rather, looking at, as much as they can, at the product features and risk, the same way that the FDA doesn't say that you have to have a red light or a long handle to hold a device.

But if that's part of the features, then there is a reason to look and see what this feature does to the safe operation of the device.

BY MS. EATON:

Q. Are you familiar with the process by which FDA establishes special controls for certain class 2 devices?

A. Yes.

Q. As part of that process, does FDA ever adopt specific standards for either a device or a test that might be used with a device?

A. There are a few standards that the FDA recognized and adopted, especially in the

Y. DAVID

cardiovascular arena.

Q. Have you looked at the classification regulation for patient warming devices?

A. Yes.

Q. Does it include any special controls?

A. No.

Q. Are you familiar with any industry standard that guides the design or manufacture of patient warming devices?

A. Except the good manufacturing practice, no.

Q. Are you aware of any hospital standard that requires filters to be present on specific patient warming devices?

A. No, I'm not aware.

Q. Are you familiar with the ventilation requirements -- I'm sorry, let me ask that differently.

Are you responsible for evaluating or implementing the ventilation requirements for hospital operating rooms?

A. As we discussed this morning, my

involvement -- my involvement in operating room design and function has evolved over the years and especially here in Texas Medical Center. The hospital I worked with, I have a responsibility for equipment planning and it was in the facility design I would be part of the operating room design team and I would be part of the room air exchanges, temperature controls, humidity --

Q. Thank you. I had forgotten that. You did say that this morning.

Would part of your role involve evaluating or selecting filtration for operating room air?

A. No. I would not select the filters.

Q. Do you have any expertise in filters?

A. Expertise? I understand their function and their construction, how they are rated, how they're being measured, so I have working knowledge of filters and filters' functionality.

Q. That working knowledge, was that

developed in connection with this case?

A. I believe that I described several times today that it's been much beyond that. In the areas of operating room design, cardiac catheterization room design, I was involved with probably 50 or 60 of those facilities and equipment planning and discussion about filtration and filters were part of the team discussion.

I did not select filters, as I said before, but that's where my working knowledge comes from.

Q. Have you ever conducted testing of a filter, any kind of testing of a filter?

A. I don't believe that I did.

Q. Have any of your work responsibilities outside of litigation involved filtration on medical devices specifically as opposed to rooms?

A. The examples that come to my mind as we sit here today are involvements that I have with mechanical ventilators and bedside monitors. Those two product categories involve both protection of the device from

penetration of bacteria from the outside as well as protection of the device from developing pathogens in the internal cavities.

Q. In what context have you worked with those two devices?

A. With the ventilators, I was invited to travel to Travemünde in Germany. That's where Dräger Medical is located and doing their research and manufacturing, and they were developing a new pediatric ventilator and wanted to have an opinion about how the clinicians and the biomedical engineers and the hospital will review their product features.

So they took the medical director of the neonatology ICU, a respiratory therapist director and myself, and we were participating in brainstorming session that looked at how the device is going to be maintained, its cleanliness, in face of some challenging environment, challenging in regard to pathogens.

The other example involved bedside monitoring, and on that product I was invited

to Redmond, Washington, to visit with Space Lab company who developed a new colored monitor for vital signs to be used in intensive care units and wanted to know if the feature of interaction with the display by physically have a touch-sensitive display are appropriate for the environment as to where the monitor will be versus where the operating will be and will -- filter changes will be technically challenged if you have to do so many steps to get to the filters.

Q. For either one of those examples, were you providing any type of microbiology or infectious disease expertise?

A. No.

Q. Have you ever tested filters for efficiency at capturing particles?

A. No.

Q. Has part of your professional responsibility outside of litigation ever involved interpreting filter efficiency testing?

A. I believe that during the project that involved the trace amount of anesthetic

gases in the operating room, we had part of our measurement the air combination level by changing the number of room air exchanges over a certain range in looking for the outcome as well as by changing filters.

Q. Were you providing expertise with respect to the filters and their effect on the air?

A. No. I was part of the team that has -- my part was different role.

Q. Are you familiar with the MERV, M-E-R-V, rating system for filters?

A. Yes.

Q. Are you familiar with that outside of your work on this case? Had you been familiar with that outside of your work on this case?

A. Yes. And MERV is an abbreviation, as you know.

Q. Is that something you used in your work outside of this case or encountered?

A. Encountered. I'm not sure that I'm using it.

Q. Have you seen indication that the

filter for the model 750 Bair Hugger device meets MERV 14 standards?

A. There is test results within the documents that I have here of testing that filter efficiency. But as I sit here, I don't recall by heart what level of MERV that would be.

Q. Do you have any opinion about what the particle capture efficiency of any Bair Hugger filter is separate from a document that you've reviewed in one of the binders sitting in front of you?

A. I don't believe that I understand your question.

Q. Do you have any information about the efficiency of a Bair Hugger filter separate from the documents that are sitting here in front of you?

A. Separate, no.

Q. Have you reviewed any hospital infection rates or records with respect to Bair Hugger use in connection -- I'm sorry, with -- let me ask a better question.

Have you reviewed any hospital

infection rates or records that you've attempted to correlate in any way to Bair Hugger use?

A. Well, my report includes a significant amount of literature on that, and I read that and drew a conclusion.

Q. Separate from the literature listed in your report, have you reviewed any?

A. Separate? I don't think so.

Q. Have you taken any action to try to remove Bair Hugger devices from any hospitals?

A. I have no authority to do that.

Q. Have you communicated to any hospital a concern about Bair Hugger use or a belief that they should take action?

A. No.

Q. Do you know if St. Luke's or Texas Children's Hospitals continue to use Bair Hugger devices?

A. I do not know.

Q. Have you contacted anyone at the FDA or the CDC with respect to the Bair Hugger device?

A. No.

Q. Do you know anyone who has had a surgery where a Bair Hugger device was used?

A. I don't believe that I know that.

Q. Do you know of any individual person who's had an infection after a Bair Hugger device was used?

A. Outside the --

Q. Information that's --

A. -- government study?

Q. Outside the information that you reviewed for this case.

A. No.

Q. Have you spoken with anyone other than plaintiffs' lawyers about the Bair Hugger device and its potential -- I'm sorry -- let me ask a better question.

Have you spoken with anyone other than plaintiffs' lawyers about the Bair Hugger device causing infections, in your opinion?

A. No.

Q. Have you spoken with anyone who you believe to be the treating physician for any plaintiff?

A. No.

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Q. Have you spoken to any healthcare facilities where you believe any of the plaintiffs in this litigation have had their surgeries performed?

A. I have no knowledge where it was performed.

Q. Have you watched the "green smoke" video prepared by Scott Augustine?

A. As I said earlier today, I watched a video, YouTube video, that Dr. Augustine prepared. I don't know if it was green or yellow, something. He has something there that I watched. I don't know what it was.

Q. Do you have any information about that test beyond what's available from viewing the YouTube video?

A. No.

Q. Did you make any inquiry into the conditions, for example, of how that test was conducted?

A. No.

Q. Does that test in any way form the basis for your opinions in this case?

A. Not at all.

Y. DAVID

Q. Have you ever reviewed the deposition transcripts of any of the study authors that are cited in your report with respect to studies about the Bair Hugger device?

A. Can you ask that again?

Q. Your report includes a citation to several articles with respect to the Bair Hugger device. Have you reviewed the deposition transcripts of any of those authors?

A. I wasn't aware that they were deposed, so no, I did not.

Q. Do you have any information that any of the authors on those studies have tried to culture bacteria coming out of a Bair Hugger system used with a blanket attached?

A. I do not have information on those studies except what's in the publication.

Q. If Dr. McGovern, for example, had tried to culture bacteria coming out of a Bair Hugger system when operated with a blanket attached and was not able to do that, would that be important to you?

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MR. BANKSTON: Object to the form.

A. I read his study. It was a large population, close -- I think over 1500 total cases. It was well executed. I don't think that I made comments to myself about trying to swab in the Bair Hugger itself. I don't recall that in the study.

BY MS. EATON:

Q. And do you recall anything in the study report saying, "We made tests to look for live bacteria in the room or in the air after the Bair Hugger was used"? Did you recall any results like that in the paper?

A. As you marked the evidence today, there are 11 binders here with material. I'm afraid I have to tell you that I cannot remember the study unless you give me time to read it.

Q. We might do that in a moment. Would it be important to you if there were tests made to determine if live bacteria came out of the Bair Hugger blanket when the system was operated as it was intended to be used? Whether those results were positive or

Y. DAVID

negative, would that be important to you?

A. Well, my report points to two mechanisms for increasing infection risk at the surgical site when Bair Hugger is used. One is the thriving of pathogens from the floor device. The other one is the interruption of unidirectional flow around the surgical site due to conduction of warm air -- warm air eddies.

So that may be one of the mechanisms, but there's another mechanism that's contributing to the Bair Hugger contribution to risk threat that you're not addressing.

Q. Would it be important to you with respect to the first mechanism that you identified if air was cultured after the Bair Hugger device was operated as a system with a blanket attached and there were no live bacteria?

MR. BANKSTON: Object to the form.

A. I believe it would be, but as I said, there are two mechanisms. This is one of the two. And there are other studies that

suggest that there were contamination in a large number of Bair Huggers that were studies. The Stanford study, for example, is one of them.

BY MS. EATON:

Q. Are you pointing to any study where the Bair Hugger device was operated as a system with its blanket and live bacterias were cultured in high levels in the air after that?

MR. BANKSTON: Object to the form.

A. No. I'm referring to culturing the Bair Huggers.

BY MS. EATON:

Q. You mean taking swabs from the inside of the units?

A. From the hose.

Q. In your hospital, were hoses used directly on patients without blankets attached?

A. I don't believe so.

Q. From your review of the operating instructions in this case, are you aware that that would be in violation of the

instructions?

A. I'm not suggesting that that's how the Bair Hugger is being used. I'm suggesting that the hose that has positive culture is connected to a blanket, so if they identify positive culture at the end of the hose that's connected to the blanket, they can probably measure positive culture if they would do it on the blanket as well.

Q. Do you know how much air force it would take to remove bacteria from the inside of a hose?

A. No.

Q. Have you identified any patient warming device that does not have a hose that runs between the unit and a blanket and serves as a connector?

A. Sure. All the conductive warming devices that use pads and have no air circulated whatsoever.

Q. There's no connection between the pad and any hardware unit?

A. There is. There's no hose.

Q. Okay. Thank you.

A. Can we have a break?

MR. BANKSTON: Yeah, we've been going over an hour and a half.

MS. EATON: Have we?

MR. BANKSTON: Yeah.

MR. GOSS: One hour.

MS. EATON: Okay. It doesn't seem that long to me.

MR. BANKSTON: The room is a little stuffy and we have an older witness. If he wants a break, I'd like to give it.

MS. EATON: That's fine.

THE VIDEOGRAPHER: We're going off the record at 16:33.

(Recess, 4:33 p.m. to 4:54 p.m.)

THE VIDEOGRAPHER: We are back on the record at 16:54.

BY MS. EATON:

Q. Dr. David, do you have any expertise in aerobiology?

A. I don't believe so.

Q. Have you ever tested the effectiveness of any laminar flow system?

A. No, I did not.

Q. Do you have any expertise in air flow or air movement?

A. Expertise, I have a very good working knowledge being in orthopedics operating room, being in the cardiovascular operating room, in general in large concentration of operating room at the Texas Medical Center. I'm talking about 60 to 65 operating rooms and be responsible for all the medical technologies in that area. I fully understand what the unidirectional flow in a protective area is all about. I fully understand design of operating room, of cardiac catheterization laboratory that I was involved with and the placement of objects within that environment.

So I have a very good working knowledge and I can explain to a layperson about it, but I don't believe that I'm expert in that area.

Q. Do you have any expertise in infectious disease?

A. No, I do not.

Q. Do you have any expertise in

surgical site infections?
A. No, I do not.
Q. Do you have any expertise in aseptic technique?
A. Again, I have good working knowledge because this would be part of my involvement in equipment that is present during surgical procedures and in trauma rooms and I will be required to oblige by techniques such as that.
Q. Is our earlier discussion today reflective of your involvement in those matters?
A. It was a specific example. My involvement is much wider because I would be walking literally daily through the operating theater, visiting with the director of the operating room, visiting with surgeons, and looking at the various devices that are being used. So I have intimate interaction with that area.
Q. Do you have responsibility -- I'm sorry, let me ask it differently.
Have you had responsibility within

hospitals for implementing infection control practices?
A. I do not believe that I have the expertise in implementing infection control practices, but as it involves equipment in areas that might have risk of infections and contamination such as intensive care unit and moving ventilators and infusion pumps from one room to another, I have been involved with a team that would implement that type of practice.
Q. Are you a medical doctor?
A. No, I'm not a medical doctor.
Q. Do you have any medical training?
A. I do not have medical training.
Q. Do you have expertise in heat transfer?
A. Being a biomedical engineer, it was one of the courses that I took as part of my academic preparation. Heat transfer is an important physical phenomenon, and I studied and understand it. And I understand the principle operation.
Q. You mentioned radiant heat earlier.

Is that one form of heat transfer?
A. Absolutely.
Q. Is conductive heat another form of transfer?
A. Correct.
Q. And is convective heat another form of transfer?
A. Like ovens, yes.
Q. Have you ever participated in an infectious disease outbreak investigation?
A. Yes.
Q. How many times?
A. Couple of times.
Q. For which hospital?
A. I'm not sure that I can discuss that. There might be some protective order there.
Q. Okay. Was that in connection -- well, was that in connection with litigation?
A. No.
Q. Both times you can remember, were they at the same hospital?
A. Yes, I believe the same hospital.
Q. Do you recall what the organism was

ultimately that was at issue?
A. No, I do not.
Q. What was your role in the investigation?
A. As the team investigate -- investigated the possible source and contributing factors, my role was to ascertain the functionality of the medical devices in it.
Q. Were any patient warming devices involved? Let me ask a different question.
Did you investigate any patient warming devices?
A. Yes, we did. We had the fluid-circulating devices at the time and they were part of the investigation.
Q. What kind of fluid-circulating device?
A. I can see the product in front of me. I don't remember the brand name.
Q. Was it the -- I did not -- I'm sorry. I didn't -- do you recall the function of the device separate from the brand name?
A. Yes. The device would heat fluids

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and circulate it through a mattress under the patient. So it would be a conduction heat.

Q. Were other sources in the operating room considered as well?

A. Yes.

Q. Can you give me examples of the other kinds of sources that were considered?

A. Ventilators, mechanical ventilator.

Q. Anything else?

A. No.

Q. From the outset there was a focus on those two pieces of equipment?

A. No. I'm just not -- feel comfortable to discuss that.

Q. Okay. Let me -- you're concerned about confidentiality, is that it? Or what do you mean by "not comfortable"?

A. Yes.

Q. Okay. I don't want to violate your confidentiality. That's not what I'm seeking to do.

Are you familiar with the principles of outbreak investigation through your work?

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A. Yes.

Q. Is there any standard that you use or refer to?

A. As one member on the team, there were other experts that that seemed to be their field of expertise, so we were given the protocol and the plan of action.

Q. Does one aspect of investigation when there's a concern about an outbreak involve taking cultures and swabs from various locations, for example?

A. Absolutely.

Q. Would that include surfaces within the room?

A. Yes.

Q. Would it include surfaces that are, for example, a countertop or a wall or a floor?

A. Yes.

Q. Would it include testing -- I'm sorry. Would it include taking samples or swabs from medical equipment that is in the room?

A. Yes.

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Q. What other types of steps would be involved in an infectious disease outbreak in a hospital setting?

A. The steps it will involve will be identifying the pathogen, see if it can be matched with patient -- with a result of patient testing, and begin to eliminate potential sources.

Q. Do you try to do that investigation as close as possible in time to when a surgical operation may have occurred?

A. It's an interesting question. However, I believe that those areas were not surgical areas.

Q. Okay. Are you familiar with the process used for doing an outbreak investigation when the area at issue is an operating room?

A. I would say it's a similar process.

Q. Okay. Are you a certified industrial hygienist?

A. No, I'm not.

Q. Have you ever published anything in peer-reviewed literature concerning what does

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or does not cause surgical site infections?

A. No, I did not.

Q. Are you aware -- actually, let me just take that back. I'm going to mark --

(Discussion off the stenographic record.)

(David Exhibit 12 marked.)

BY MS. EATON:

Q. This is a June 1, 2000 letter that I believe you've reviewed. Is that correct?

(Document review by witness.)

BY MS. EATON:

Q. Have you seen this before?

A. Yes.

Q. Okay. If you would look at the fourth paragraph, please.

A. Okay.

Q. The last sentence in that paragraph says, "With this amendment, the filters in our currently cleared devices (including the SE Device Model 505) and the Model 750, will all be 0.2-micron filters."

Do you see that sentence?

A. Yes.

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Q. Does anything about this letter describe to the FDA what efficiency of capture at the .2-micron size the filter will have?

A. Well, the second paragraph is saying that the air filter described is HEPA filter in their submission and that was the plan. But due to certain accessibility to material, that filter is not available.

However, we know that it's not just the filter but also the pressure drop that was difficult for the 750.

Q. Maybe my question wasn't clear. I'm asking if there's anything about this letter --

A. And --

Q. -- that you take -- were you going to get to the question?

A. Yes.

Q. Okay.

A. So I'm trying to answer your question by saying that, first of all, there is indication that HEPA filter is there and there is no change from filter characteristics. Paragraph 2 and 3 are saying

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that. And paragraph 3 is saying it will be 2.2-micron, so the impression is, is .2-micron with same efficiency, when one reads this letter.

Q. Are you aware of anyplace in this letter or otherwise where any company made a representation to the FDA about what percentage capture of particulates of the .2-micron size a Bair Hugger filter would have?

A. I believe when you called a filter a HEPA, high-efficiency particle arrestor, you are designating the efficiency of 99.97% --

Q. Is it your interpretation of this --

A. -- at .2 micron.

So when you read this letter, you are getting the impression that that's the area we are addressing, that level of efficiency.

Q. You read this letter to be the company telling the FDA that the Bair Hugger devices will have a HEPA filter? That's how you read this letter?

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A. No. I'm saying that the preliminary paragraph, it's simply, look, the first paragraph saying we have submission and we would like to amend it. The second paragraph's saying we talked about HEPA filter and we're going to get something that is similar. The third paragraph said, I cannot get this but it will be similar characteristics. The last line on the third paragraph specifically says we want to have the option to use our current filter characteristics, and then they go to the .2 micron without any additional description.

So if it's different than that, why don't you say it's different? If it's the same, then that's what you started the letter with.

Q. So you believe that the second paragraph in this letter says to you that the existing filters on the Bair Hugger devices are HEPA filters?

MR. BANKSTON: Objection to form.

A. I believe that what I'm saying is

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that it will be the same as the SE device as the 500 series, which was close to HEPA.

BY MS. EATON:

Q. Where in this letter does it say the 500 series filter was close to HEPA?

A. Where? I have 10 binders here we marked up with information saying that that's the filter in the 500 series.

Q. A HEPA filter?

MR. BANKSTON: Object to the form.

A. I didn't say HEPA.

BY MS. EATON:

Q. I'm trying to understand what you're saying because what you're saying is not appearing to me in this letter. Are you saying you have all these binders --

A. No problem.

Q. -- of material that say that the filter in the 505 was close to HEPA?

A. Right. The drop from M10 to M20, I think they called it, specific brand, is significant drop in efficiency. But what I'm saying is the material I have here is saying that the 505 filter has 90% efficiency

at .2-micron, and the 750 submission was saying we're going to have much higher flow rate and we're going to have a better filter, it will be HEPA filter. But then a week later, hey, listen, Mr. FDA, I cannot get it but I'll get something that is similar to what the 500 is.

The 500 is 90% efficiency. It doesn't say here that .2-micron would have 50% or less efficiency as it came out to be.

Q. So if we would look at the letter that is in front of you, the paragraph that I first referred to, the fourth paragraph, begins by saying, "We want to amend the 510(k) to include a filter that is substantially equivalent to the filter currently being used in all of our cleared devices."

Do you see that sentence?

A. Yes.

Q. Okay. With respect to the "currently" -- I'm sorry. With respect to the filter that was being used in 500 series devices, is there anywhere you can point me to that the company told the FDA what percentage

efficiency that filter would have at a .2-micron level?

A. I'll be happy to do that. I can start looking at the material.

Q. Well, I don't want to take the time to have you look at material, so I'm just -- let me ask this differently.

MR. BANKSTON: Object to the form.

BY MS. EATON:

Q. If the FDA wished to take action against the company for its filter, what percentage efficiency at the .2-micron level would be the threshold below which there would be a problem?

A. If you're saying at the third paragraph that we have option to use the current filter characteristics and you're saying in the fourth paragraph it will be a substantial equivalent to the filter currently being used on all our cleared devices, that is clear indication that we're going to use a filter that is better than 90% efficient at .2-micron. That's not what happened after this letter.

Q. Was the efficiency of capture at a .2-micron level a design input for this product?

A. I believe design input was a HEPA filter to begin with, so it was better than that.

Q. Let's look at the 500 series. Was efficiency of capture of a percentage at .2-micron-size particle part of the design input for the 500 series products?

A. I did not see the design input characteristics. I saw the outcome, and the outcome is a filter that has better than 90% efficiency at .2-micron.

Q. Was the capture efficiency at .2-micron a specification in the 510(k) submission for the 500 series devices?

A. I don't understand what you mean by "specification." It is a feature of the system.

Q. Okay. There is a sentence in this document that says, "The change to add the filter with the SE" -- let me ask this differently.

When would -- what percentage reduction in capture of particles at the .2-micron size would result in a filter no longer being substantially equivalent?

A. Excellent question. I would love to see a study that would answer that. We don't have one.

Q. What information would you need to know that you don't know?

A. A clinical study in operating room that do orthopedic surgery with such a filter conducted by infectious disease expert.

Q. Okay.

(Sotto voce discussion.)

BY MS. EATON:

Q. Are you aware of any -- let me say this differently. Are you aware of any clinical data that establishes a different infection risk based on filter characteristics for a Bair Hugger device?

A. I don't believe that as I sit here today I'm prepared to tell you that I'm aware of -- I can search for it, because what I am aware of is that the large amount of

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publication are talking specifically about the relationship between filter effectiveness and increased threat of surgical site infection.

And as a matter of fact, we have standards, and in this case I have a policy example from M.D. Anderson, a well-known hospital, that are saying that we have to have filters with HEPA efficiency in those protective environment where the threat of infection in orthopedic surgery is higher than in other locations.

So I'm not here sitting today and can point to here's the study. I can do my homework and find it for you. But I'm saying that the ample data that I am providing here to you today is suggesting that the less efficient the filter is, the higher the threat of infection at the surgical site. There's a simple relationship.

Q. What study, in your mind -- are you able to cite me to a single study, sitting here today, that would establish what you just said?

MR. BANKSTON: Object to the form.

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A. In the McGovern study, they have the Bair Hugger and when they removed it and used another patient warming device, there was 81% reduction in infection. With the Bair Hugger, there was 3.8 index increased probability of infection.

At the incident with the literature review that I cited in my report, looking at all the studies, the conclusion was simple that a HEPA filter is one of the ways to mitigate infection. The CDC article that I have in my publication also talks about filtering level efficiency. They -- the literature from orthopedics, Bone & Joint Journal, is talking about one of the solution is increase filter efficiency.

So there's ample evidence out there that there is a relationship between filter efficiency and the potential risk of infection at the surgical site.

BY MS. EATON:

Q. Would a 75% capture of .2-micron particles change the clinical risk as opposed to a 90% capture of .2-micron particles?

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A. Counsel, this is an excellent question and I think that the manufacturer of a device who has filters in such environment should do the study and bring the solution, bring the answer. If the solution is there's no difference, use the filter that has only 70%. If the solution is, oh, my God, this is real problem, you better change the filter or change the product. But that's exactly where we are today is that we do not have a properly conducted double-blind study of infection rates in orthopedic surgeries where air-warming -- forced-air warming devices were used and it should be done if a manufacturer is considered to be prudent and care for patient safety.

Q. What size are the bacteria that cause surgical site infections?

A. Look. I have Dr. Hogg's paper here and it has an exact size. You want the viruses that are smaller than 1 microns, you have bacteria between 1 and 6 microns, fungi is above that. We can go back and forth about how much I remember of all this material, but

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this information is today in the public domain. I don't have to be expert about that.

Q. But I do want to understand what your expertise is. Did you mean Dr. Ho?

A. Ho, yeah.

Q. Have you reviewed his report?

A. Report, I've reviewed -- it's in my report here, I've reviewed it --

Q. I don't believe it is. I don't think it would have even been available to you at the time you prepared your report, but you've mentioned his name more than once. And so I --

A. Okay, so I take your word for it. I learned about it after I wrote my report.

Q. Well, one thing we have -- there have been several times today when you've mentioned either transcripts or reports that you believe you've reviewed that are not in front of us, and I -- Mr. Ulatowski is one I know for sure; I do believe in the morning Dr. Ho may have been another.

Is there someplace you can check for me to determine if you have some

additional materials that you have reviewed that are maybe not here today?

A. There's no additional material. We covered that subject totally. Ulatowski is one that is missing here. It will be added to the -- Dr. Ho, maybe it was after my report was written.

Q. I'm just wanting to make sure I understand all the materials you've reviewed. So if there's a place where you're -- could you take a look when you return to your home or office and just see if there perhaps are other materials that you have reviewed?

A. I certainly can do this, Counsel, and I will be happy to oblige. I can tell you that I made an effort to have all the material here today with us and I believe it is, except Tim Ulatowski.

Q. Okay. Sitting here today for purposes -- let me ask that differently.

For purposes of coming to your opinions in this case, did you rely on any understanding about what size bacteria cause surgical site infections?

A. For arriving at my opinion in this case, I fully appreciate the difference in sizes and the intensity of bioburdens of viruses, bacteria, fungi, as it relates to surgical site infection. I did not use that to arrive at my opinion. My opinions are biomedical engineering and risk assessment based.

Q. In assessing the risk that a difference in filtration at .2-micron size makes, what did you consult?

A. I consulted the literature, the medical and scientific literature, and I consulted the responses to answers by the defendant officers to a specific question about this subject.

Q. And are all the materials that you've just referenced identified in your report?

A. Absolutely.

Q. Okay. Did you conduct a literature search yourself?

A. The literature that I present in my report are a combination of my search and

counsel providing me with some.

Q. Are you able to tell me which items were provided by counsel?

A. Specifically which ones, no, I don't.

Q. And if you would open up, please, the binder that has literature in it just so that we could take a look at the specific index, whichever binder that is. I think it may be the one in your hand, I don't know. No? Sorry.

A. This is the one.

Q. Okay. Just see if by taking a look at that list you can identify any items that you believe were provided by counsel.

A. I would say that all those that has a numerical number at the end, 3MBH, a number that no question provided to me by counsel.

Q. Anything else?

(Document review by witness.)

A. I don't remember exactly, but some title like Forced Air Warming Blower Evaluation would be a title that I would come up and search and ask.

BY MS. EATON:

Q. Could I see the binder for one moment?

A. (Complies.)

Q. Thank you, sir.

What search terms did you use -- I'm sorry, let me ask that differently. What -- tell me about the search you conducted.

A. Well, I went on PubMed and visited the Texas Medical Center library and looked at mostly forced-air warming devices, and if there is something about filter efficacy. So this study is talking about evaluation, probably I picked it up in my search.

Q. Okay. Do you recall or did you record anywhere what search terms you used?

A. What search terms? No, I did not record that.

Q. Do you recall how many articles came back in response to your search terms?

A. Not really, no.

Q. Did you review the abstracts for all articles that came back in response to the

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search terms you used?

A. If it got late at night, I probably did not read all the abstracts but I made an effort to go through them and request those that I seemed to think applicable. I have -- I remember reading abstract from "Anesthesia," the journal, that looks like something I would like to have, but it ended up that the abstract was not really useful for me.

Q. What -- did you have any prespecified criteria for what an article needed to have before it would be one you would consider relevant?

A. No.

Q. What was your research question?

A. I'm not sure that I have research question.

Q. What was your -- what kind of article were you looking for?

A. I was looking for a comparative article, article that would have a good research design, hopefully similar environment, large population, and peer-reviewed.

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Q. Okay. What would it be comparing, what to what?

A. I wanted to see. I didn't have a pre-notion about what should be there.

Q. What were you looking to find out from these articles?

A. The level of knowledge within the professional community of the relationship between forced-air warming devices and surgical infection during orthopedic surgery; the possible methods that are used to identify that; the span of instrumental devices that are mentioned in those articles. That's about it.

Q. Okay. Are you familiar with the term "systematic literature review"?

A. Yes.

Q. That's not what you conducted.

A. Correct.

Q. Would you agree?

A. Correct.

(Sotto voce discussion.)

MS. EATON: What time is left on the record?

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THE REPORTER: We're at 6:17 right now.

MR. BANKSTON: Let's go off the record for just one second.

(Discussion off the stenographic record.)

THE VIDEOGRAPHER: We're going off the record at 17:36.

(Recess, 5:36 p.m. to 5:37 p.m.)

THE VIDEOGRAPHER: We're back on the record at 17- -- wait a minute.

We're back on the record at 17:37.

BY MS. EATON:

Q. When you reviewed the literature, did you locate any articles that evaluated whether the use of the Bair Hugger device increased the risk of infection and found that it did not?

A. Just to make sure that I understand your question, you're saying the article talked about increased infection but the conclusion or the finding was that it was not?

Q. Yes, that the test question was whether it would increase the risk of

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infection and it did not.

A. I don't think so.

Q. Did you locate any articles that concluded specifically that the Bair Hugger device decreased the risk of surgical site infection?

(Document review by witness.)

A. One of the articles that I indicate and consider is the review article of existing literature by Wood, Moss and Keenan, and I'm not sure, I need to read the study again, but maybe one of the articles there was saying there was no difference. I don't think that there was decrease, but no difference. I just need to read that paper again.

BY MS. EATON:

Q. If there were articles that established that the -- I'm sorry. If there were articles that reported that the use of a forced-air warming device during surgery decreased the risk of surgical site infection, would that be relevant to your consideration?

A. It would.

Q. If there were articles

demonstrating that there were no clinically significant increases in particle count with the use of a Bair Hugger or forced-air warming device, would that be relevant to your opinions?

A. It would. But again, Counsel, you remember that I incorporate into my opinion two routes. Two routes. The particle count is one way to increase the threat of infection but there is the heat itself --

Q. Yes.

A. -- as another path.

Q. And if you had located any article that would demonstrate the use of a Bair Hugger device did not interfere with laminar flow, would that be relevant to your opinions?

A. Yes.

Q. Have you been provided with any of the reports of defense experts in this case, other than potentially Dr. Ho?

A. Outside what I have here, no. I don't have anything that was not included.

Q. When you were selecting articles to include in your report, did you specifically

select only those that had a conclusion that supported your opinion that the Bair Hugger device has the potential to increase infection risk?

A. That's a nice gentle way to suggest that I preselected the articles, but no, I select articles based on the concept of the use of forced warm air device and infection. So those that I have in my report are the articles that they came back.

Q. So if there are articles that would not support an inclusion -- if there are articles that would not support a conclusion that the Bair Hugger device might increase surgical site infection risk, they're not included because you didn't find them?

MR. BANKSTON: Object to the form.

A. I -- I don't know if there are studies of quality and peer-review journal that suggest what you're saying, but if there are, I would like to read them.

BY MS. EATON:

Q. Are you familiar with an article with the first author Kurz, K-U-R-Z?

A. What's the title of the article?

Q. I am not sure by heart. I have it.

THE VIDEOGRAPHER: Christin, I think your mic popped off. It only goes so far.

MS. EATON: Sorry.

THE VIDEOGRAPHER: That's okay.

MS. EATON: Thank you for letting me know.

BY MS. EATON:

Q. "Perioperative Normothermia to Reduce the Incidence of Surgical-Wound Infection and Shorten Hospitalization."

A. The heading doesn't seem like something that would fall within my search.

Q. Does that mean you believe you did or didn't see this article?

A. That probably I did not see it.

Q. Okay. Why would it not fall within your search?

A. Because I provided you the route I took to look specifically at engineering, biomedical engineering type of information relating to infection and this type of patient

warming device. So what you are pointing at probably would not come in my search. Would not come up in my search.

Q. Thank you for that clarification.

Did you make any attempt to assess the clinical benefit that may be provided by normothermia in any respect?

A. I believe that the benefit is discussed in many studies. I don't have to go into these clinical issues.

Q. Do you dispute that the maintenance of normothermia or the prevention of hypothermia results in clinical benefit?

A. For specific patient conditions, I do not.

Q. Is there a surgical -- okay, let me say that differently.

You're familiar that one of the recommended infection control practices for surgery is to maintain normothermia?

MR. BANKSTON: Object to the form.

A. Yes, Counsel, but I believe we talked about cooling down patients during a cardiovascular procedure and bypass of the

heart where specifically you're cooling down patients. I don't believe you want to maintain normothermia in those patients. So I agree with you that certain patient conditions would -- seems to benefit from normothermia, but not all patients.

BY MS. EATON:

Q. Setting aside cardiovascular surgery, any other surgery that you would separate out?

A. I'll have to think about it. I did not prepare myself to respond to that.

Q. Did you make any investigation related to evaluating the potential infection reduction that could result from the use of forced-air warming?

A. I believe you're asking me a clinical question that was not my objective.

Q. Did you make any evaluation of the clinical -- okay, let me say that differently.

What do you mean by that, what you just said?

MR. BANKSTON: Object to the form.

A. What I mean by that is simply that

my charge was to look at the Bair Hugger 750 from hazard and risk control issues, not from clinical outcomes, the type of question you have for me.

BY MS. EATON:

Q. Okay. So making a medical causation determination is not something that you set out to do.

A. Medical causation is not -- what I am prepared to do is to offer the opinion that the Bair Hugger 750, when it is operating in orthopedic surgical procedures, more likely than not will contribute to a higher risk of surgical site infection.

Q. Than what?

A. More likely than not.

Q. As compared to what? I may have misunderstood you.

A. I don't think that I compared it to.

Q. Let me read the answer.

(Counsel reviewing realtime transcript on the reporter's computer.)

--oOo--

BY MS. EATON:

Q. Will contribute a higher risk than if it were not used?

A. Correct.

Q. Is the interpretation of clinical study data about infection risk something that you have ever done outside of your work in a lawsuit?

A. Can you ask it again?

Q. Outside of your work for a lawsuit, is the interpretation of clinical study data concerning infection risk something that you do?

A. In my work, I'm expected to read clinical literature and scientific publication. I am educated, trained, and have the experience to understand the study structure and the strength of the conclusions.

And in my evaluation of various medical devices, at the hospital I worked for for over 25, 30 years, part of the process was to review current medical and scientific literature relating to device performance and bring that to what in my report describe as

MTEC, M-T-E-C, Medical Technology Evaluation Committee, that looked at the overall what you asked earlier, benefit-to-risk ratios and understand what the product risk based on the information from the manufacturers, but also based on experience that comes from clinical studies that published in peer-reviewed journals.

Q. If the use of a forced-air warming device decreases infection risk, would that be relevant to a clinical benefit-risk assessment?

A. Yes.

Q. Okay. In your work -- well, you -- have you ever -- more probable than not, is that a scientific standard?

A. Yes.

Q. Okay. Is there anyplace in an engineering standard that you say more probable than not is the criteria?

A. Many times.

Q. Can you identify one?

A. Can I make a joke in a casino?

Yes. For example, when the Space

Y. DAVID

Shuttle Challenger disaster happened, I followed clearly -- sorry. I followed intimately the investigation because I wanted to see what they are doing relating to discovery of risk, and one of the team members were talking about more probably than not, this part was subjected to cold temperature below the span of specification.

So yes, it's a nonengineering term.

Q. In terms of making a comparison of the likelihood that one patient warming device would change the infection risk as compared to another patient warming device, have you included in your report everything that you reviewed?

A. Yes.

Q. Is there any clinical data you're aware of that would suggest there's a difference in infection risk between the Bair Hugger device and any other patient warming device that you have identified in your report?

A. I didn't find it, so everything that I did is in my report.

Y. DAVID

Q. Did you find any studies that suggested the risk was not different between the Bair Hugger device and another type of patient warming device?

A. No, I did not.

Q. Did you look?

A. I believe that I did look and the literature did not have a simultaneously double-blind study with two different products. What they come close to is what I have here, was the McGovern, of removing the Bair Hugger and using something else. And it's clearly -- a clear indication of the improvement in the rate of infection when the Bair Hugger was not there.

Q. Yet you didn't put the HotDog device in your report, right?

MR. BANKSTON: Object to the form.

BY MS. EATON:

Q. We can move on because that's already established.

Are you aware of any information about the underlying data from the McGovern study?

Y. DAVID

A. Underlying data? I've read the article. I understand how it was conducted, how the data was collected. If there's something beyond the study information, no, I don't know.

Q. Have you ever taken any course in epidemiology or biostatistics?

A. I don't think that I have epidemiology courses. I had the courses in engineering about statistics.

Q. Do you consider yourself an expert in biostatistics?

A. No, I'm not.

Q. Okay. Do you consider yourself an expert in epidemiology?

A. No, I'm not.

Q. Okay. Do you have any familiarity with the concept of confounding as it might impact study results?

A. I'm familiar with the concept, yes.

Q. Okay. Did you make any evaluation of the McGovern study and how they did or did not attempt to control for confounding?

A. I read that. I think that the

Y. DAVID

conclusions were important for me and the study contained large enough population to be significant and published in peer-reviewed journal.

Q. And would you agree with the authors of the McGovern study that this study does not establish a causal basis for an association between the type of warming device and infection risk?

A. I read that part, yes.

Q. And do you agree with it?

A. I agree with their conclusions, yes.

Q. Why did that part not make it into your report?

MR. BANKSTON: Object to the form.

A. I beg a difference with you because the study is included. My report is having the take-home comments from myself.

BY MS. EATON:

Q. Did every single article that you reviewed include a similar statement that the study did not establish a causal association between use of the Bair Hugger device and an

Y. DAVID

increase in infection risk?

A. I don't believe I followed your question.

MS. EATON: Could you read that back?

(The reporter read back the following portion of the preceding record.)

"QUESTION: Did every single article that you reviewed include a similar statement that the study did not establish a causal association between use of the Bair Hugger device and an increase in infection risk?"

(End of readback.)

A. I understand the comment you're making. The studies that I read are specifically concluding with measurements and effect of what they found out relating to the device, Bair Hugger. So that was my focus and interest to know as far as the risk associated with that.

If there is a comment about not having association, that -- that left that for

Y. DAVID

the clinician.

BY MS. EATON:

Q. And if the authors of a study said that their study did not establish that the Bair Hugger device or a forced-air warming device caused an increase in infection, would you defer to them on that?

A. I would defer to them, yes.

MS. EATON: What is my record time?

THE REPORTER: 6:40, ma'am.

BY MS. EATON:

Q. Okay. With respect to the potential modifications to the Bair Hugger device identified on pages 35 to 37 of your report, do you have any information beyond what you have included in your report about the feasibility of these alternatives?

A. These alternatives represent a very significant effort by 3M engineers to explore different solution to the problem that we are discussing here today. The feasibility looks to me to be within the reasonable range with...

(Document review by witness.)

Y. DAVID

BY MS. EATON:

Q. I'm just asking you if you have anything beyond what you've put in your report.

A. No.

Q. Are you aware that any of these designs have ever been implemented by 3M or any other company?

A. My understanding, they have not. The management refused to implement them.

Q. Is it your understanding that prototypes were developed that would have been workable in practice?

A. My understanding that some of the alternatives represented in these pages became a prototype.

Q. Is your understanding based only on the materials that you've reviewed in this case?

A. Correct.

Q. Were you provided with the deposition of Winston Tan?

A. If it's not noted in my report, I did not. I was not.

Y. DAVID

Q. What data establishes that any of the alternative products identified in your report are safer than the Bair Hugger device?

A. That's an excellent question, and I believe that I address that. Because as I'm looking at alternative design, I'm describing three paths. One is to add something to the product. The other one is to remove, or a third way, to re-engineer the device in a different way. These devices that I mention are in several different physical principles of operation. Conductions, convections, and no forced air at all but rather using electrical pad is one of the criteria that I just mentioned.

So if you have articles that I mention in my report that are suggesting that removal of the Bair Hugger reduce infections by 81% like McGovern is saying, or the potential for cultures will be dropped like the Stanford study is saying with cleaning or removing of those products, then changing from forced air open-ended through perforation of the blanket to recirculated air to HEPA filter

with warning to a non-air-use electric pads to a nonmoving blanket with much smaller air flow rate that does not disturb the unidirectional flow in the operating room, all provide for significant improvement in smaller amount of risk exposure and uninterrupting unidirectional flow in the OR. Those are two principles that I described in my report.

Q. Are you an expert in the relationship between particles and bacteria or infection risk?

A. Expert in the relationship between particle and bacteria. While I do not understand your question, I don't pretend to be expert in relationship between particle and bacteria.

Q. Okay. Did you look for any clinical data on any of the three devices identified in your report that might indicate their performance or infection risk?

A. The literature support my argument. Even 3M that bought Vital Health, in their disclosure to a press release saying that this is safe and effective device and would

supplement the product that they have. And when you do not have warm air circulating but it's a closed loop, I don't think that you need to be an expert to realize that you're removing a threat. You therefore are reducing exposure to the risk.

Q. Are you familiar with the concept that direct contact with a surface can pose an infection risk?

A. That makes sense.

Q. Is that something that you're familiar with in your work in the hospitals?

A. Well, hand hygiene is a typical example. Very, very known in hospitals.

Q. And reusable medical equipment that directly touches patients, that's also an example?

A. Well, it's not the same because most of the accessories that will touch patients will be disposable, single use, and probably sterile. So that's not the same as hands touching surfaces.

Q. Have you provided in your report all of the data that you reviewed with respect

to the alternative products that you've identified?

A. Yes, I did.

MS. EATON: Do I have any time left?

THE REPORTER: You're at 6:48.

MS. EATON: Okay. I'm going to reserve.

MR. BANKSTON: Yeah, I'm a little hot so we'll take a literally two- or three-minute break.

THE VIDEOGRAPHER: We're going off the record at 18:08.

(Recess, 6:08 p.m. to 6:17 p.m.)

THE VIDEOGRAPHER: We are back on the record at 18:17.

EXAMINATION

BY MR. BANKSTON:

Q. Dr. David, you were asked some questions about risk-benefit. Do you remember those questions?

A. I do.

Q. Okay. First of all, is it your opinion that the Bair Hugger should be taken

out of rooms and not replaced with any form of patient warming?

A. No.

Q. Okay. Are there other devices available, other design concepts which are feasible to be made without the same risk mechanism that you identified in your report?

MS. EATON: Object to the form of the question.

A. Right. I indicated in my report and so is my opinion that I identify specific product with different features that remove the risk introduced by the Bair Hugger 750 and yet serve the purpose of controlling patient temperature environment.

BY MR. BANKSTON:

Q. Does the literature you reviewed contain any studies or any opinions concerning whether any of these devices are similar in effectiveness to the Bair Hugger at maintaining patient temperature?

A. I was trying to scan in my memory where that might be in my report.

Q. Let me know.

A. And I think that --
Q. Well, can I direct you to a page maybe that I want to ask you about?
A. In the --
Q. Let me withdraw that -- let me withdraw that question, Dr. David. Can we take a look at your report? Can you flip to page 39 for me?
MS. EATON: And I'll just object to this as leading.
MR. BANKSTON: Okay.
BY MR. BANKSTON:
Q. Do you see a reference on 39 to Dr. Daniel Sessler?
A. Yeah, that's the one I was looking for, actually.
Q. Who is Dr. Daniel Sessler? What role does he play?
A. I understand that he was or is clinical consultant to 3M and might be working with other vendors.
Q. Did you rely on Dr. Sessler's opinions in any respect in this case?
A. Well, one thing that his study was

supportive is that resistant heating mattresses are of equal efficiency to the Bair Hugger forced-air blanket in maintaining temperature, and that's why I incorporate that study here.
Q. Okay. From your engineering background and experience, do you have any opinion on whether, apart from these four devices, just from an engineering concept standpoint, is it possible, more likely than not, to design a device that does not pose the risks you've identified but warms patients as effectively?
MS. EATON: Object to the form of the question.
A. These devices that I show as alternatives are demonstrating that. 3M engineers have several concepts that they came up with. One of them is the, I believe, recirculating, is basically what I have in my alternative design, so it is feasible.
BY MR. BANKSTON:
Q. Okay. You were asked some questions about speaking to hospitals about

Bair Hugger risk. Do you remember those questions?
A. Yes.
Q. Okay. When you began work on this case, did you sign a protective order?
A. I did.
Q. Okay. Did you review confidential materials in this case?
A. I did.
Q. Did you rely on any confidential materials in coming to your conclusions in this case?
A. Yes.
Q. Do you have any understanding of what will happen to you if you disclose 3M's confidential information in the things you've learned in this case?
A. I understand, and that's part why I didn't discuss that with hospitals.
Q. You take those obligations seriously in terms of protecting 3M's corporate property?
A. I do.
Q. When you, in your career, have been

evaluating medical devices for healthcare facilities, did you come to any understandings during those days regarding whether certain procedures had unique vulnerabilities to infection?
MS. EATON: Object to the form of the question.
A. There is no question that after so many years in the largest medical center in the country, as I worked in, you get exposed to condition of patients from A to Z and there are variation. There are patients that come in with sore throat and would go home. There are patients that come in with a brain tumor and it will be very difficult to deal with that.
So there are environments that are much more susceptible to condition that the patients are in than others, and specifically orthopedic surgery is one of those environments.
BY MR. BANKSTON:
Q. I would like to show you a document that's been previously marked in this

Y. DAVID

litigation as Exhibit 47. Can you take a look at that document for me?

MS. EATON: Can you tell me what you're looking at?

MR. BANKSTON: Why don't you take a look at it before he does. Should be able to -- it's a 510(k) summary of the 505 series.

MS. EATON: Thank you.

BY MR. BANKSTON:

Q. Dr. David, this is a document you reviewed and relied on in this case?

MS. EATON: Objection to the form.

A. Yes.

BY MR. BANKSTON:

Q. Okay. Can you take a look at the second page there?

A. Okay.

Q. Do you see a spot on there where the highlight is on filter density?

MS. EATON: Objection to the form.

A. Yes, I do.

BY MR. BANKSTON:

Q. Okay. Can you explain why filter

Y. DAVID

density was important to you in terms of this document?

MS. EATON: Objection to the form.

A. Filter density is one of the characteristics describing the filter features and it is important because the less dense filter will be less efficient.

BY MR. BANKSTON:

Q. In this document, in this 510(k) application or summary, whatever the word you want to use for it is, are two Bair Hugger devices being described and their filter density?

A. Correct.

MS. EATON: Objection to the form.

BY MR. BANKSTON:

Q. Did you gain any understanding from this document whether the 500 series Bair Hugger and the 505 series Bair Hugger have the same filter density?

A. That's what this document is suggesting.

Q. Do you know, sitting here today, whether these --

Y. DAVID

MS. EATON: Just let me interject an objection to the form.

BY MR. BANKSTON:

Q. Do you know sitting here today whether the 700 series has the same filter density as the 500 series?

A. I know that it does not. It has less efficient.

Q. Okay. Thank you, Dr. David. Let's put that back in your book so we don't lose it.

Dr. David, you were asked about another document today in your materials section. It has been previously marked in this litigation as Exhibit 48 [Exhibit 12]. You remember this letter?

MS. EATON: Is this the one we previously discussed?

MR. BANKSTON: This is the one you offered into evidence, yes.

MS. EATON: I didn't offer it into evidence, just to be clear. I asked him to look at it.

MR. BANKSTON: Oh, I'm sorry, I

Y. DAVID

didn't know that you didn't offer it into evidence. I thought everything that was marked was going into evidence on the books. Is that not what we're -- we're not going to put all the materials in?

MS. EATON: I'm certainly not aware of any protocol for offering anything into evidence. I simply asked him to review something.

MR. BANKSTON: All right. Let's go ahead -- no, actually, that's previously marked so I don't mind.

BY MR. BANKSTON:

Q. Dr. David, I'm showing you what's been marked previously in this litigation as Exhibit 48 [Exhibit 12]. Do you remember discussing this letter today?

A. Yes.

Q. Okay. Do different filters have different characteristics or do all filters have the same characteristics?

A. Oh, no. There's a wide span in different characteristics between the filters.

Y. DAVID

Q. Is the efficiency of a filter one of its characteristics?

A. Very important characteristic.

Q. If a device manufacturer reduced the filtration efficiency of one of its filters but told the FDA that we'd still be using, quote, "our current filter characteristics," is that honest?

MS. EATON: Objection to the form, foundation.

A. That is absolutely misleading.

BY MR. BANKSTON:

Q. Okay. If you knew or had been exposed to articles discussing a decrease in surgical site infection in certain procedures such as, say, a colorectal surgery, would that have any application to your opinions regarding the risk of infection in orthopedic surgeries?

MS. EATON: Objection to the form.

A. I feel that the orthopedic surgeries are a specific area of surgical procedures. They are longer, they are more complex. They are more susceptible to

Y. DAVID

infection, and there's no correlation between colorectal procedures and orthopedic surgical procedure.

BY MR. BANKSTON:

Q. Okay. There was some testimony today about the literature review conducted by Dr. Wood and his associates. Do you know which study I'm referring to there?

A. Yes.

Q. Okay. In that review, was there information -- did it simply include studies that were unfavorable to the Bair Hugger or did it also include some studies that claimed to be favorable to the Bair Hugger?

MS. EATON: Objection to the form.

A. As I sit here today, I don't remember all the studies. There are probably 15. He looked at what's available in the literature at the time he conducted his study, but those are the -- representative of the knowledge that was in the field at that time.

BY MR. BANKSTON:

Q. Okay. You're familiar -- we've discussed much today -- there are multiple

Y. DAVID

models of the Bair Hugger?

A. Yes.

Q. Okay. If there are articles out there discussing bacterial sampling with a previous model 500 series instead of a model 700 series, can you tell me if or if not that would have any direct engineering application to your opinions about the model 700 series in this case?

MS. EATON: Objection to the form.

A. It's very important because the features of those two families of product, the 750 and the 500, are different from engineering perspectives in that the filter characteristic is different and the volume of flow air pushed through them is also greatly different.

BY MR. BANKSTON:

Q. Dr. David, can you pull out your report for me and flip to page 20?

A. I'm there.

Q. Do you see at the top references to some scientific work by Hall and by Zink?

A. Yes, I do.

Y. DAVID

Q. Are you familiar with what these studies are?

A. Yes.

Q. Okay. Can you briefly explain what the context of these studies are?

A. Yes. I read those articles. Hall is talking about, I believe, eight volunteers that were subjected to a culture count, and Zink is talking about, I believe, 16 patients that were in a completely different environment than orthopedics procedure.

Q. Dr. David, can you tell -- can you tell the jury generally what your impression of your task in this case was?

A. Absolutely. And I actually put it as the first paragraph in my report, that my task was to review the hazards and risk associated with the Bair Hugger 750 family and to opine about if that would contribute to unreasonable dangerous biomedical engineering device that increase the probability of infection in orthopedics procedure or not.

Q. Okay. Can you tell me a little bit -- no, let me take that back. In coming

to an opinion about the -- whether a device more likely than not does or does not pose a patient risk, can you briefly summarize to the jury what you believe qualifies you to render those kind of opinions?

A. That would be an easy task, Counsel. That's something that I have been doing for over 30 years, especially at the Texas Medical Center where I worked 25 years. I was director -- I was the chairman of medical technology evaluation committee with the specific task of reviewing new technology and make recommendation to the hospitals should they acquire and invest in that technology because it will have benefit of lower risk of existing device or increasing patient outcome because of positive feature that they represent.

My committee consists of many representative stakeholders; physicians, nurses, purchasers, administrators, safety officers, risk control and quality control professionals, and facilities engineering, biomedical engineering, and sterile processing

supplies.

So the committee was representing so many expertise and I was in the position where I had to receive their input and derive recommendation to the hospital management if a device is beneficial with lower risk than what is being used today or until that product come.

So I believe that I have the qualification based on academic training and experience working with these stakeholders and with this group to specifically evaluate and assess risk-benefit ratios.

Q. Do you feel like you have enough materials to give yourself an informed and helpful opinion that you can communicate to the jury?

A. I do. And when I felt that I don't have enough material, I approached you, Counsel, and requested specific documents or information. So I'm comfortable that I received the material that I need to arrive at the opinions.

Q. And do you feel confident today

that your opinions were delivered to a reasonable degree of engineering probability?

A. I do.

MR. BANKSTON: Okay. That's all I have. You can pass -- pass the witness.

FURTHER EXAMINATION

BY MS. EATON:

Q. Okay. Let's -- I just have a couple of things but perhaps let's go off the record for one second so I can organize myself.

THE VIDEOGRAPHER: We are going off the record at 18:34.

(Recess, 6:34 p.m. to 6:38 p.m.)

THE VIDEOGRAPHER: We are back on the record at 18:38.

BY MS. EATON:

Q. Dr. David, did you consult with any medical expert in connection with your work in this case?

A. No, I did not.

Q. Have you spoken with anyone who you believe to be an expert witness for any party in this case?

A. No, I did not.

Q. Okay. In performing your work for the hospitals, did you rely on physicians and nurses to provide you with information about clinical risks and benefits?

A. On the clinical side, yes.

Q. Do you understand that it was your responsibility, in preparing your report, to express all of the opinions that you would intend to offer at trial?

A. I do.

Q. And did you also understand that it was your responsibility to provide the bases for those opinions?

A. Yes.

Q. Did you endeavor to do that?

A. Absolutely.

Q. Okay. Are the statements that are contained in your report accurate to the best of your knowledge?

A. They are.

Q. Okay. Is there any prohibition on your discussing published literature with the hospital, to your understanding?

Y. DAVID

A. I'm trying to understand your question. Prohibition on published hospital...

Q. If you had an interpretation of published literature about a forced-air warming device or any other device, would you be free to talk to a hospital about that?

A. During this litigation, I don't feel so.

Q. You simply can't speak at all about patient warming devices, to your interpretation?

MR. BANKSTON: Object to the form.

A. As it relates to the condition of this litigation, yes, that's the way I feel.

BY MS. EATON:

Q. Okay. Did you review an ECRI evaluation of the potential risk of infection with Bair Hugger use?

A. Yes.

Q. Did you cite that in your report?

A. Good question. I don't think so.

Q. Do you believe you reviewed it before you wrote your report or after?

Y. DAVID

A. After.

Q. Okay. Do you believe you reviewed it -- can you tell me when you reviewed it?

A. I became aware that they made a report and wanted to understand what they considered, so I would say probably in the last month or so.

Q. Are there any other materials related to this case that you reviewed in the last month that we haven't discussed here today and have not been identified for me today?

A. No.

Q. Okay. Did you agree with the conclusion of ECRI?

A. I believe they attempted to understand the condition. They're operating in a different environment than I am, and they concluded that what I believe is that additional studies are needed.

Q. They concluded that there was not sufficient evidence to determine that there was an increased risk with the Bair Hugger device, right?

Y. DAVID

MR. BANKSTON: Object to the form.

A. The way I understand their document or what I read is that they have not find material to recommend the discontinued use of the Bair Hugger and that additional studies are required to better address that issue.

BY MS. EATON:

Q. Did you disagree with anything about the method they used to identify information they reviewed?

A. No.

Q. Did they use a more comprehensive method than you used to identify literature?

A. Counsel, they are doing different things than I'm doing. I think that I mentioned that this is a different environment. They have a relationship with industry, with hospital as customers, and they're looking at an overall.

I have specific charge to my work. I'm not studying the complete concept of what is patient warming is all about. I have specifically charge as mentioned in the opening of my report.

Y. DAVID

Q. Are you familiar with the proceedings of the international consensus meeting on periprosthetic joint infection? Is this something you've ever reviewed?

A. Can I look at it?

Q. Sure. Well, I mean, it's not cited in your report, and I just wondered if this is something that you recognize.

A. No.

Q. Did you make any attempts to look for industry evaluations or medical evaluations of the risk-benefit balance of the Bair Hugger device by an association, for example, or an organization?

A. I think in my search I looked for that, yes.

Q. Do you have any idea why you wouldn't have found the ECRI compilation or the proceedings of the periprosthetic joint infection? Is there something about your search that wouldn't have resulted in that?

A. I don't think that the way I see that title, joint infection, would be something that would fall into my search.

Y. DAVID

Q. Okay. Were you looking specifically for literature that related to the risk of joint infection following surgery?

A. No, I did not.

Q. Is it your testimony that orthopedic surgery carries a higher risk of infection than colorectal surgery?

A. It is my opinion that they are completely different conditions and present different challenges and cannot be compared.

Q. Do you know if the infection risk for orthopedic surgery is higher or lower than the infection risk for colorectal surgery?

MR. BANKSTON: Objection, form.

A. No, I don't have that knowledge.

BY MS. EATON:

Q. Do you have any knowledge about what the risk of infection is with any type of surgery?

A. I believe that I read recent statistics about that. Where was it... general statistics I read have the hospital-acquired infection, HAI, statistics relating to surgery. I don't remember as I

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sit here today specific numbers or quantities.

Q. Okay. Are you an expert in -- I'm sorry. Have you made any -- have you made any effort to study, in connection with your work for this case, what are the various risk factors that might impact infection risk in a patient during surgery?

A. When I read the articles, it was obvious that the beginning of the literature talk about the specific basic of infection routes and the sources. So every time I was reading the articles, it addressed that very clearly.

Q. In terms of all the things that might impact patient infection risk from a medical perspective, that's not something you're offering opinions about?

A. I am not.

Q. Have you seen a 500 series filter?

A. I don't know what you mean by "seen." I saw a drawing and I saw pictures in brochures.

Q. Okay. Do you recall what shape it is?

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A. It's different than the 750.

Q. Does it differ in size also from the 750?

A. It does.

Q. Have you done any comparison yourself of the filters?

A. There's no need for me to do it. Other expert did that.

Q. Who are you referring to?

A. The literature here in front of us has ample support material for that, so Hanfield is one, three -- letters, letters from defendant officers is another one that --

Q. I'm asking about anything you did, other than review materials.

MR. BANKSTON: Object to the form.

BY MS. EATON:

Q. Did you make a comparison of the two filters? Maybe --

A. There is --

Q. You only looked at a drawing of the 500 series filter. Is that correct?

A. Right.

Q. Okay. Do you recall what shape it

Y. DAVID

was?

MR. BANKSTON: Object to the form.

A. Yeah.

BY MS. EATON:

Q. What shape was it?

A. Square.

Q. Do you recall the -- I'm sorry, what? Do you recall the size of it?

A. I didn't realize I'm in a memory test here. Shape, geometry, size, it's all in the material here. It's all described in detail. It is part of the binders that I have. If you want to take the time, I will go through the material and find it.

Q. I'd rather ask you a question about your report. If you --

MR. BANKSTON: Object to the preamble.

BY MS. EATON:

Q. Do you have any -- actually, what is the basis for your opinion that the Bair Hugger device is adulterated and misbranded? What specific features of it?

A. Very simply, the company misled the

FDA by suggesting that they are a comparable product, that they changed characteristics of major components like the filter, did not communicate that, and yet marketed the device to consumer, confusing and misleading them.

Q. Do you have any basis for an opinion about industry standard other than compliance with FDA regulation?

A. In regard to what?

Q. In regard to the opinions you've expressed in your report.

MR. BANKSTON: I think we're done, Counsel.

MS. EATON: Could we just have an answer to this question?

MR. BANKSTON: Well, you're already past it but I was trying to give you some grace. But you started asking more questions after you've already passed the --

MS. EATON: I don't believe I've asked any question after I was past anything.

Could we have that question read

back, please.

MR. BANKSTON: Can we get the time first?

THE REPORTER: It's 7:01:42-43 at this point.

(The reporter read back the following portion of the preceding record.)

"QUESTION: Do you have any basis for an opinion about industry standard other than compliance with FDA regulation?

"ANSWER: In regard to what?

"QUESTION: In regard to the opinions you've expressed in your report?"

(End of readback.)

A. I'll have to search that.

MR. BANKSTON: All right. I've got a few more questions.

FURTHER EXAMINATION

BY MR. BANKSTON:

Q. This -- do you mind if I see that? Do you remember being asked about this?

A. Yes.

Q. And counsel wouldn't give it to you?

A. Correct.

Q. Because she said it wasn't in your report?

A. Right.

MS. EATON: Object to the form. I didn't say I wouldn't give it to him. I asked him if he recognized it.

MR. BANKSTON: And then you said he's not getting it because it's not in his report.

MS. EATON: He said, no, he didn't recognize it.

BY MR. BANKSTON:

Q. Counsel -- Dr. David, do you remember counsel telling you this wasn't in your report?

A. Yes.

Q. Okay. Can you go to page 48 for me. Can you read the fourth entry from the bottom for me?

A. "International consensus meeting on

periprosthetic joint infection."

Q. Okay. So that is something you reviewed in this case?

MS. EATON: Objection to the form.

A. If it's listed here as document, yes.

BY MR. BANKSTON:

Q. The depositions that you reviewed in this case, did they have exhibits to them?

A. Yes.

Q. Do you remember in any of the depositions in this case or in more than one or none of them, was ECRI ever discussed in those depositions?

A. Yes.

Q. Now, in your report, you did not specifically list each and every exhibit of every deposition I see. That's correct?

A. Correct.

MS. EATON: Object to the form.

BY MR. BANKSTON:

Q. Okay. When reading the depositions that had exhibits, those exhibits that are discussed in the deposition, those are parts

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of the transcripts that you've read?

MS. EATON: Object to the form.

A. Absolutely.

BY MR. BANKSTON:

Q. The exhibits in the depositions that you reviewed, did you consider them important in coming to your opinions?

MS. EATON: Object to the form.

A. Yes.

BY MR. BANKSTON:

Q. The exhibits that are in the depositions, do you consider them as materials that you have reviewed in coming to your opinions in this case?

A. Very much so, yes.

MR. BANKSTON: Okay.

MS. EATON: Object to the form.

MR. BANKSTON: And we get to go home, Dr. David.

MS. EATON: No, sir. I have a few follow-up questions because what I've been provided doesn't include any exhibits at all and so I definitely have some questions.

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MR. BANKSTON: You can go to the Court for those.

MS. EATON: I have a few follow-up questions.

MR. BANKSTON: No, you don't. We're going.

MS. EATON: Well, I'm going to ask and you --

MR. BANKSTON: I'm going to tell you what's going to happen. We're going to go because Dr. David needs to go and he has a prior engagement. If you feel like you need to reconvene the deposition, you can attempt to do that through whatever legal avenues you believe are appropriate. But I can tell you what's going to happen right now is at 7:00 p.m., when you began a deposition late and have taken a lot of time preparing in between stuff, we're going to go right now. So that's what's going to happen.

MS. EATON: For the record, the documents that have been provided for me

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here today do not include any exhibits at all, and I've received repeated assurances that I have --

MR. BANKSTON: That's strange because my --

MS. EATON: They don't -- they're not contained with the depositions and I've asked if I've received all the materials and I've been told repeatedly yes. So I'd just make a request that we have a search for any additional materials that may have been reviewed because it would appear that there are quite a few that may be missing.

MR. BANKSTON: All right. If you really think that you are hair-splitting enough to say that a person who has read depositions did not also review the exhibits that were discussed in the text of the deposition, I think that's an asinine position. I think providing notice of what depositions were --

MR. GOSS: Let's not get into any name-calling.

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MR. BANKSTON: Well, it is and I keep getting this kind of thing, so I'm going to --

MR. GOSS: Put it on the record. Your objection is noted. I think we know where we stand on this --

MR. BANKSTON: That's right.

MR. GOSS: -- hopefully the position that he has --

MR. BANKSTON: Right. As though a counsel would not know to ask about things discussed in a deposition when the depositions are listed in the materials reviewed, and that's why we're heading out today.

MS. EATON: Okay.

THE VIDEOGRAPHER: Christin, is that it?

MS. EATON: Yes.

MR. BANKSTON: Thank you, lady and gentlemen. This concludes the deposition. We're going off the record at 18:55.

(Time noted: 6:55 p.m.)

C E R T I F I C A T E

STATE OF TEXAS)

COUNTY OF HARRIS)

I, SUSAN PERRY MILLER, CSR, CCR, RDR, CRR, CRC, Notary Public in and for the State of Texas, do hereby certify:

That YADIN DAVID, Ed.D., P.E., C.C.E., the witness whose deposition is hereinbefore set forth, was duly sworn by me and that such deposition is a true record of the testimony given by the witness;

That pursuant to Rule 30 of the Federal Rules of Civil Procedure, signature of the witness was not reserved by the witness or other party before the conclusion of the deposition;

I further certify that I am not related to any of the parties to this action by blood or marriage; and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 11th day of August, 2017.

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SUSAN PERRY MILLER, RDR, CRR, CRC

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---------- EXHIBITS ----------

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ERRATA SHEET FOR THE TRANSCRIPT OF: YADIN DAVID, Ed.D., P.E., C.C.E.
Case Name: In Re: Bair Hugger Products Liability Litigation
Dep. Date: August 1, 2017
Deponent: YADIN DAVID, Ed.D., P.E., C.C.E.

Pg.	Ln.	Now Reads	Should Read	Reason

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Signature of Deponent

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